

Suspend the Rules and Pass the Bill, HR. 6378, with An Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

115TH CONGRESS
2D SESSION

H. R. 6378

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 16, 2018

Mrs. BROOKS of Indiana (for herself, Ms. ESHOO, Mr. WALDEN, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on the Judiciary, Veterans' Affairs, and Homeland Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To reauthorize certain programs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act with respect to public health security and all-hazards preparedness and response, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 SECTION 1. SHORT TITLE.

2 This Act may be cited as the “Pandemic and All-Haz-
3 ards Preparedness and Advancing Innovation Act of
4 2018”.

5 SEC. 2. TABLE OF CONTENTS.

6 The table of contents of this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

**TITLE I—STRENGTHENING NATIONAL PREPAREDNESS AND
RESPONSE FOR PUBLIC HEALTH EMERGENCIES**

Sec. 101. Coordination of preparedness for and response to all-hazards public health emergencies.

Sec. 102. Public health emergency medical countermeasures enterprise.

Sec. 103. National Health Security Strategy.

Sec. 104. Improving emergency preparedness and response considerations for children.

Sec. 105. Reauthorizing the National Advisory Committee on Children and Disasters.

Sec. 106. National Disaster Medical System.

Sec. 107. Volunteer Medical Reserve Corps.

Sec. 108. Continuing the role of the Department of Veterans Affairs.

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Sec. 110. National Advisory Committee on Individuals with Disabilities and Disasters.

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Sec. 115. Improvement of loan repayment program for prevention activities.

Sec. 116. Report on adequate national blood supply.

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**TITLE II—OPTIMIZING STATE AND LOCAL ALL-HAZARDS
PREPAREDNESS AND RESPONSE**

Sec. 201. Public health emergencies.

Sec. 202. Improving State and local public health security.

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Sec. 204. Improving benchmarks and standards for preparedness and response.

Sec. 205. Public health and health care system situational awareness and bio-surveillance capabilities.

Sec. 206. Authorization of appropriations for Emergency System for Advanced Registration of Volunteer Health Professionals.

Sec. 207. Regional health care emergency preparedness and response systems.

- Sec. 208. National Academy of Medicine evaluation and report on the preparedness of hospitals, long-term care facilities, dialysis centers, and other medical facilities for public health emergencies.
- Sec. 209. Limitation on liability for volunteer health care professionals.

TITLE III—ACCELERATING MEDICAL COUNTERMEASURE
ADVANCED RESEARCH AND DEVELOPMENT

- Sec. 301. Strategic national stockpile and security countermeasure procurement.
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TITLE IV—MISCELLANEOUS PROVISIONS

- Sec. 401. Cybersecurity.
- Sec. 402. Miscellaneous FDA amendments.
- Sec. 403. Medical countermeasure master files.
- Sec. 404. Formal strategy relating to children separated from parents and guardians as a result of “zero tolerance” policy.
- Sec. 405. Biological threat detection.
- Sec. 406. Strengthening mosquito abatement for safety and health.
- Sec. 407. Additional strategies for combating antibiotic resistance.
- Sec. 408. Additional purposes for grants for certain trauma centers.
- Sec. 409. Review of the benefits of genomic engineering technologies and their potential role in national security.
- Sec. 410. Cut-Go offset.

1 TITLE I—STRENGTHENING NA-
2 TIONAL PREPAREDNESS AND
3 RESPONSE FOR PUBLIC
4 HEALTH EMERGENCIES

5 SEC. 101. COORDINATION OF PREPAREDNESS FOR AND RE-
6 SPONSE TO ALL-HAZARDS PUBLIC HEALTH
7 EMERGENCIES.

8 (a) IN GENERAL.—Section 2811 of the Public Health
9 Service Act (42 U.S.C. 300hh–10) is amended—

10 (1) in subsection (b)—

11 (A) in paragraph (4)—

12 (i) in subparagraph (G)—

1 (I) by inserting “the pandemic
2 influenza and emerging infectious dis-
3 ease program established under sec-
4 tion 319L(d), or” before “all-hazards
5 medical and public health prepared-
6 ness and response”; and

7 (II) by adding at the end (after
8 and below clause (ii)) the following:

9 “Such drills and operations exercises shall be
10 comprehensive, synchronized, and mutually sup-
11 portive.”; and

12 (ii) by adding at the end the following
13 new subparagraph:

14 “(I) THREAT AWARENESS.—Coordinate
15 with the Director of the Centers for Disease
16 Control and Prevention, the Director of Na-
17 tional Intelligence, the Secretary of Homeland
18 Security, the Assistant to the President for Na-
19 tional Security Affairs, the Secretary of De-
20 fense, and other relevant Federal officials, such
21 as the Secretary of Agriculture, to maintain a
22 current assessment of national security threats
23 and inform preparedness and response capabili-
24 ties based on the range of the threats that have

1 the potential to result in a public health emer-
2 gency.”;

3 (B) in paragraph (5), by adding at the end
4 the following: “Such logistical support shall in-
5 clude working with other relevant Federal,
6 State, local, tribal, and territorial public health
7 officials and private sector entities to identify
8 the critical infrastructure assets, systems, and
9 networks needed for the proper functioning of
10 the health care and public health sectors that
11 need to be maintained through any emergency
12 or disaster, including entities capable of assist-
13 ing with, responding to, and mitigating the ef-
14 fect of a public health emergency, including a
15 public health emergency declared by the Sec-
16 retary pursuant to section 319, or an emer-
17 gency or major disaster declared by the Presi-
18 dent pursuant to the Robert T. Stafford Dis-
19 aster Relief and Emergency Assistance Act or
20 the National Emergencies Act, including by es-
21 tablishing methods to exchange critical informa-
22 tion and deliver products consumed or used to
23 preserve, protect, or sustain life, health, or safe-
24 ty, and sharing of specialized expertise.”;

25 (C) in paragraph (7)—

1 (i) in the matter preceding subpara-
2 graph (A)—

3 (I) by inserting “the research
4 and development activities of the pan-
5 demic influenza and emerging infec-
6 tious disease program established
7 under section 319L(d) with respect to
8 qualified pandemic or epidemic prod-
9 ucts (as defined in section 319F–3),
10 and” before “the medical counter-
11 measure priorities described in sub-
12 section (d)”; and

13 (II) by striking “Develop, and
14 update not later than March 1 of each
15 year” and inserting “Develop, by not
16 later than September 30, 2019, and
17 update not less than annually after
18 the initial development,”; and

19 (ii) in each of subparagraphs (D) and
20 (E), by striking “not later than March 15
21 of each year” and inserting in each such
22 place “not later than 14 days after each
23 biennial development date”; and

24 (D) by adding at the end the following new
25 paragraph:

1 “(8) REPORTING.—The Assistant Secretary for
2 Preparedness and Response shall, beginning on the
3 date of the enactment of this paragraph, submit to
4 the Committee on Energy and Commerce of the
5 House of Representatives weekly reports on the sta-
6 tus and welfare of the children who, as a result of
7 the ‘zero tolerance’ policy, were separated from their
8 parent or guardian and are awaiting reunification
9 with their parent or guardian, as well as the number
10 of such children in facilities funded by the Depart-
11 ment of Health and Human Services.”;

12 (2) in subsection (c), in the matter preceding
13 paragraph (1), by striking “shall” and inserting
14 “shall, utilizing experience related to public health
15 emergency preparedness and response, biodefense,
16 medical countermeasures, and other relevant topics”;
17 and

18 (3) in subsection (d)—

19 (A) in paragraph (1), by striking “Not
20 later than 180 days after the date of enactment
21 of this subsection, and every year thereafter”
22 and inserting “Not later than September 30,
23 2019, and every second year thereafter”;

24 (B) in paragraph (2)(C), by inserting after
25 “products” the following: “, and ancillary med-

1 ical supplies to assist with the utilization of
2 such products,”; and

3 (C) in paragraph (2)(J)(v), by striking
4 “the one-year period for which the report is
5 submitted” and inserting “the two-year period
6 for which the report is submitted”.

7 (b) COUNTERMEASURES BUDGET PLAN.—Section
8 2811(b)(7) of the Public Health Service Act (42 U.S.C.
9 300hh–10(b)(7)), as amended by subsection (a)(1)(C), is
10 further amended—

11 (1) by striking subparagraph (A) and inserting
12 the following:

13 “(A) include consideration of the entire
14 medical countermeasures enterprise, includ-
15 ing—

16 “(i) basic research and advanced re-
17 search and development;

18 “(ii) approval, clearance, licensure,
19 and authorized uses of products;

20 “(iii) procurement, stockpiling, main-
21 tenance, and potential replenishment (in-
22 cluding manufacturing capabilities) of all
23 products in the Strategic National Stock-
24 pile;

1 “(iv) the availability of technologies
2 that may assist in the advanced research
3 and development of countermeasures and
4 opportunities to use such technologies to
5 accelerate and navigate challenges unique
6 to countermeasure research and develop-
7 ment;

8 “(v) development of clinical guidance
9 for use of medical countermeasures; and

10 “(vi) postmarket evaluation of the
11 safety and efficacy of medical counter-
12 measures used pursuant to an emergency
13 use authorization under section 564 of the
14 Federal Food, Drug, and Cosmetic Act.”;

15 (2) by redesignating subparagraphs (D) and
16 (E) as subparagraphs (E) and (F), respectively; and

17 (3) by inserting after subparagraph (C) the fol-
18 lowing:

19 “(D) identify the full range of anticipated
20 medical countermeasure needs related to re-
21 search and development, procurement, and
22 stockpiling, including the potential need for in-
23 dications, dosing, and administration tech-
24 nologies, and other countermeasure needs as
25 applicable and appropriate;”.

1 **SEC. 102. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
2 **TERMEASURES ENTERPRISE.**

3 Subtitle B of title XXVIII of the Public Health Serv-
4 ice Act (42 U.S.C. 300hh–10 et seq.) is amended—

5 (1) by redesignating section 2811A as 2811B;
6 and

7 (2) by inserting after section 2811 the fol-
8 lowing:

9 **“SEC. 2811A. PUBLIC HEALTH EMERGENCY MEDICAL COUN-**
10 **TERMEASURES ENTERPRISE.**

11 “(a) IN GENERAL.—The Secretary shall establish
12 and the Assistant Secretary for Preparedness and Re-
13 sponse shall convene an interagency panel of advisors to
14 be known as the Public Health Emergency Medical Coun-
15 termeasures Enterprise (in this section referred to as the
16 ‘PHEMCE’).

17 “(b) MEMBERS.—In addition to the Assistant Sec-
18 retary for Preparedness and Response, who shall serve as
19 chair, the PHEMCE shall include the following members:

20 “(1) The Director of the Biomedical Advanced
21 Research and Development Authority (or the Direc-
22 tor’s designee).

23 “(2) The Director of the Centers for Disease
24 Control and Prevention (or the Director’s designee).

25 “(3) The Director of the National Institutes of
26 Health (or the Director’s designee).

1 “(4) The Commissioner of Food and Drugs (or
2 the Commissioner’s designee).

3 “(5) The Secretary of Defense (or the Sec-
4 retary’s designee).

5 “(6) The Secretary of Homeland Security (or
6 the Secretary’s designee).

7 “(7) The Secretary of Agriculture (or the Sec-
8 retary’s designee).

9 “(8) The Secretary of Veterans Affairs (or the
10 Secretary’s designee).

11 “(9) The Secretary of State (or the Secretary’s
12 designee).

13 “(10) The Director of National Intelligence (or
14 the Director’s designee).

15 “(11) The Director of the Central Intelligence
16 Agency (or the Director’s designee).

17 “(12) Representatives of any other Federal
18 agencies, as the Assistant Secretary for Prepared-
19 ness and Response determines appropriate.

20 “(c) FUNCTIONS.—The PHEMCE shall—

21 “(1) advise the Assistant Secretary for Pre-
22 paredness and Response regarding research, develop-
23 ment, and procurement of security countermeasures
24 (as defined in section 319F–2(c)) based on the
25 health security needs of the United States; and

1 “(2) assist the Assistant Secretary for Pre-
2 paredness and Response in the identification of gaps
3 in public health preparedness and response related
4 to such security countermeasures and challenges to
5 addressing such needs (including any regulatory
6 challenges).”.

7 **SEC. 103. NATIONAL HEALTH SECURITY STRATEGY.**

8 Section 2802 of the Public Health Service Act (42
9 U.S.C. 300hh-1) is amended—

10 (1) in subsection (a)—

11 (A) in paragraph (1)—

12 (i) by striking “2014” and inserting
13 “2018”; and

14 (ii) by striking the second sentence
15 and inserting the following: “Such Na-
16 tional Health Security Strategy shall de-
17 scribe potential emergency health security
18 threats and identify the process for achiev-
19 ing the preparedness goals described in
20 subsection (b) to be prepared to identify
21 and respond to such threats and shall be
22 consistent with the national preparedness
23 goal (as described in section 504(a)(19) of
24 the Homeland Security Act of 2002), the
25 National Incident Management System (as

1 defined in section 501(7) of such Act), and
2 the National Response Plan developed pur-
3 suant to section 504 of such Act, or any
4 successor plan.”;

5 (B) in paragraph (2), by inserting before
6 the period at the end of the second sentence the
7 following: “, and an analysis of any changes to
8 the evidence-based benchmarks and objective
9 standards under sections 319C–1 and 319C–2”;
10 and

11 (C) in paragraph (3)—

12 (i) by striking “2009” and inserting
13 “2022”;

14 (ii) by inserting “(including gaps in
15 the environmental health and animal
16 health workforces, as applicable), describ-
17 ing the status of such workforce” after
18 “gaps in such workforce”;

19 (iii) by striking “and identifying strat-
20 egies” and inserting “identifying strate-
21 gies”; and

22 (iv) by inserting before the period at
23 the end “, and identifying current capabili-
24 ties to meet the requirements of section
25 2803”; and

1 (2) in subsection (b)—

2 (A) in paragraph (2)—

3 (i) in subparagraph (A), by striking
4 “and investigation” and inserting “inves-
5 tigation, and related information tech-
6 nology activities”;

7 (ii) in subparagraph (B), by striking
8 “and decontamination” and inserting “de-
9 contamination, relevant health care serv-
10 ices and supplies, and transportation and
11 disposal of medical waste”; and

12 (iii) by adding at the end the fol-
13 lowing:

14 “(E) Response to environmental hazards.”;

15 (B) in paragraph (3)—

16 (i) in the matter preceding subpara-
17 graph (A), by striking “including mental
18 health” and inserting “including phar-
19 macies, mental health facilities,”;

20 (ii) in subparagraph (F), by inserting
21 “or exposures to agents that could cause a
22 public health emergency” before the pe-
23 riod; and

24 (iii) by amending subparagraph (G) to
25 read as follows:

1 “(G) Optimizing a coordinated and flexible
2 approach to the emergency response and med-
3 ical surge capacity of hospitals, other health
4 care facilities, critical care, trauma care (which
5 may include trauma centers), and emergency
6 medical systems, which may include the imple-
7 mentation of guidelines for regional health care
8 emergency preparedness and response systems
9 under section 319C–3.”;

10 (C) in paragraph (5), by inserting “and
11 other applicable compacts” after “Compact”;
12 and

13 (D) by adding at the end the following:

14 “(9) ZOONOTIC DISEASE, FOOD, AND AGRI-
15 CULTURE.—Improving coordination among Federal,
16 State, local, tribal, and territorial entities (including
17 through consultation with the Secretary of Agri-
18 culture) to prevent, detect, and respond to outbreaks
19 of plant or animal disease (including zoonotic dis-
20 ease) that could compromise national security result-
21 ing from a deliberate attack, a naturally occurring
22 threat, the intentional adulteration of food, or other
23 public health threats, taking into account inter-
24 actions between animal health, human health, and
25 animals’ and humans’ shared environment as di-

1 rectly related to public health emergency prepared-
2 ness and response capabilities, as applicable.

3 “(10) GLOBAL HEALTH SECURITY.—Assessing
4 current or potential health security threats from
5 abroad to inform domestic public health prepared-
6 ness and response capabilities.”.

7 **SEC. 104. IMPROVING EMERGENCY PREPAREDNESS AND**
8 **RESPONSE CONSIDERATIONS FOR CHIL-**
9 **DREN.**

10 Part B of title III of the Public Health Service Act
11 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
12 tion 319D the following:

13 **“SEC. 319D–1. CHILDREN’S PREPAREDNESS UNIT.**

14 “(a) ENHANCING EMERGENCY PREPAREDNESS FOR
15 CHILDREN.—The Secretary, acting through the Director
16 of the Centers for Disease Control and Prevention (re-
17 ferred to in this subsection as the ‘Director’), shall main-
18 tain an internal team of experts, to be known as the Chil-
19 dren’s Preparedness Unit (referred to in this subsection
20 as the ‘Unit’), to work collaboratively to provide guidance
21 on the considerations for, and the specific needs of, chil-
22 dren before, during, and after public health emergencies.
23 The Unit shall inform the Director regarding emergency
24 preparedness and response efforts pertaining to children
25 at the Centers for Disease Control and Prevention.

1 “(b) EXPERTISE.—The team described in subsection
2 (a) shall include one or more pediatricians, which may be
3 a developmental-behavioral pediatrician, and may also in-
4 clude behavioral scientists, child psychologists, epidemiolo-
5 gists, biostatisticians, health communications staff, and
6 individuals with other areas of expertise, as the Secretary
7 determines appropriate.

8 “(c) DUTIES.—The team described in subsection (a)
9 may—

10 “(1) assist State, local, tribal, and territorial
11 emergency planning and response activities related
12 to children, which may include developing, identi-
13 fying, and sharing best practices;

14 “(2) provide technical assistance, training, and
15 consultation to Federal, State, local, tribal, and ter-
16 ritorial public health officials to improve prepared-
17 ness and response capabilities with respect to the
18 needs of children, including providing such technical
19 assistance, training, and consultation to eligible enti-
20 ties in order to support the achievement of measur-
21 able evidence-based benchmarks and objective stand-
22 ards applicable to sections 319C–1 and 319C–2;

23 “(3) improve the utilization of methods to in-
24 corporate the needs of children in planning for and

1 responding to a public health emergency, including
2 public awareness of such methods;

3 “(4) coordinate with, and improve, public-pri-
4 vate partnerships, such as health care coalitions pur-
5 suant to sections 319C–2 and 319C–3, to address
6 gaps and inefficiencies in emergency preparedness
7 and response efforts for children;

8 “(5) provide expertise and input during the de-
9 velopment of guidance and clinical recommendations
10 to address the needs of children when preparing for,
11 and responding to, public health emergencies, includ-
12 ing pursuant to section 319C–3; and

13 “(6) carry out other duties related to prepared-
14 ness and response activities for children, as the Sec-
15 retary determines appropriate.”.

16 **SEC. 105. REAUTHORIZING THE NATIONAL ADVISORY COM-**
17 **MITTEE ON CHILDREN AND DISASTERS.**

18 Section 2811B of the Public Health Service Act, as
19 redesignated by section 102(1), is amended—

20 (1) in subsection (b)(2), by inserting “, mental
21 and behavioral,” after “medical”;

22 (2) in subsection (d)—

23 (A) in paragraph (1), by striking “15” and
24 inserting “25”; and

1 (B) by striking paragraph (2) and insert-
2 ing the following:

3 “(2) REQUIRED NON-FEDERAL MEMBERS.—The
4 Secretary, in consultation with such other heads of
5 Federal agencies as may be appropriate, shall ap-
6 point to the Advisory Committee under paragraph
7 (1) at least 13 individuals to perform the duties de-
8 scribed in subsections (b) and (c), including—

9 “(A) at least 2 non-Federal professionals
10 with expertise in pediatric medical disaster
11 planning, preparedness, response, or recovery;

12 “(B) at least 2 representatives from State,
13 local, tribal, or territorial agencies with exper-
14 tise in pediatric disaster planning, prepared-
15 ness, response, or recovery;

16 “(C) at least 4 members representing
17 health care professionals, which may include
18 members with expertise in pediatric emergency
19 medicine; pediatric trauma, critical care, or sur-
20 gery; the treatment of pediatric patients af-
21 fected by chemical, biological, radiological, or
22 nuclear agents and emerging infectious dis-
23 eases; pediatric mental or behavioral health re-
24 lated to children affected by a public health
25 emergency; or pediatric primary care; and

1 “(D) other members as the Secretary de-
2 termines appropriate, of whom—

3 “(i) at least one such member shall
4 represent a children’s hospital;

5 “(ii) at least one such member shall
6 be an individual with expertise in schools
7 or child care settings;

8 “(iii) at least one such member shall
9 be an individual with expertise in children
10 and youth with special health care needs;
11 and

12 “(iv) at least one such member shall
13 be an individual with expertise in the needs
14 of parents or family caregivers, including
15 the parents or caregivers of children with
16 disabilities.

17 “(3) FEDERAL MEMBERS.—The Advisory Com-
18 mittee under paragraph (1) shall include the fol-
19 lowing Federal members or their designees:

20 “(A) The Assistant Secretary for Pre-
21 paredness and Response.

22 “(B) The Director of the Biomedical Ad-
23 vanced Research and Development Authority.

24 “(C) The Director of the Centers for Dis-
25 ease Control and Prevention.

1 “(D) The Commissioner of Food and
2 Drugs.

3 “(E) The Director of the National Insti-
4 tutes of Health.

5 “(F) The Assistant Secretary of the Ad-
6 ministration for Children and Families.

7 “(G) The Administrator of the Health Re-
8 sources and Services Administration.

9 “(H) The Administrator of the Federal
10 Emergency Management Agency.

11 “(I) The Administrator of the Administra-
12 tion for Community Living.

13 “(J) The Secretary of Education.

14 “(K) Representatives from such Federal
15 agencies (such as the Substance Abuse and
16 Mental Health Services Administration and the
17 Department of Homeland Security) as the Sec-
18 retary determines appropriate to fulfill the du-
19 ties of the Advisory Committee under sub-
20 sections (b) and (c).

21 “(4) TERM OF APPOINTMENT.—Each member
22 of the Advisory Committee appointed under para-
23 graph (2) shall serve for a term of 3 years, except
24 that the Secretary may adjust the terms of the Advi-
25 sory Committee appointees serving on the date of

1 enactment of the Pandemic and All-Hazards Pre-
2 paredness and Advancing Innovation Act of 2018, or
3 appointees who are initially appointed after such
4 date of enactment, in order to provide for a stag-
5 gered term of appointment for all members.

6 “(5) CONSECUTIVE APPOINTMENTS; MAXIMUM
7 TERMS.—A member appointed under paragraph (2)
8 may serve not more than 3 terms on the Advisory
9 Committee, and not more than 2 of which may be
10 served consecutively.”;

11 (3) in subsection (e), by adding at the end “At
12 least one meeting per year shall be an in-person
13 meeting.”;

14 (4) by redesignating subsection (f) as sub-
15 section (g);

16 (5) by inserting after subsection (e) the fol-
17 lowing:

18 “(f) COORDINATION.—The Secretary shall coordinate
19 activities authorized under this section and section 2811C,
20 in accordance with section 2811C(d).”; and

21 (6) in subsection (g), as so redesignated, by
22 striking “2018” and inserting “2023”.

1 **SEC. 106. NATIONAL DISASTER MEDICAL SYSTEM.**

2 (a) PURPOSE OF SYSTEM.—Clause (ii) of section
3 2812(a)(3)(A) of the Public Health Service Act (42 U.S.C.
4 300hh–11(a)(3)(A)) is amended to read as follows:

5 “(ii) be present at locations, and for
6 limited periods of time, specified by the
7 Secretary on the basis that the Secretary
8 has determined that a location is at risk of
9 a public health emergency during the time
10 specified, or there is a significant potential
11 for a public health emergency.”.

12 (b) REVIEW OF THE NATIONAL DISASTER MEDICAL
13 SYSTEM.—Section 2812(b)(2) of the Public Health Serv-
14 ice Act (42 U.S.C. 300hh–11(b)(2)) is amended to read
15 as follows:

16 “(2) JOINT REVIEW AND MEDICAL SURGE CA-
17 PACITY STRATEGIC PLAN.—

18 “(A) REVIEW.—Not later than 180 days
19 after the date of enactment of the Pandemic
20 and All-Hazards Preparedness and Advancing
21 Innovation Act of 2018, the Secretary, in co-
22 ordination with the Secretary of Homeland Se-
23 curity, the Secretary of Defense, and the Sec-
24 retary of Veterans Affairs, shall conduct a joint
25 review of the National Disaster Medical System.
26 Such review shall include—

1 “(i) an evaluation of medical surge ca-
2 pacity, as described in section 2803(a);

3 “(ii) an assessment of the available
4 workforce of the intermittent disaster-re-
5 sponse personnel described in subsection
6 (c);

7 “(iii) the capacity of the workforce de-
8 scribed in clause (ii) to respond to all haz-
9 ards, including capacity to simultaneously
10 respond to multiple public health emer-
11 gencies and to respond to a nationwide
12 public health emergency;

13 “(iv) the effectiveness of efforts to re-
14 cruit, retain, and train such workforce; and

15 “(v) gaps that may exist in such
16 workforce and recommendations for ad-
17 dressing such gaps.

18 “(B) UPDATES.—As part of the National
19 Health Security Strategy under section 2802,
20 the Secretary shall update the findings from the
21 review under subparagraph (A) and provide rec-
22 ommendations to modify the policies of the Na-
23 tional Disaster Medical System as necessary.”.

24 (c) DIRECT HIRE AUTHORITY.—Section 2812(c)(1)
25 of the Public Health Service Act (42 U.S.C. 300hh–

1 11(c)(1)) is amended by inserting “(or, for the period be-
2 ginning on the date of the enactment of the Pandemic and
3 All-Hazards Preparedness and Advancing Innovation Act
4 of 2018 and ending on September 30, 2021, without re-
5 gard to those provisions of title 5, United States Code,
6 governing appointments in the competitive service)” after
7 “in accordance with applicable civil service laws and regu-
8 lations”.

9 (d) SERVICE BENEFIT; NOTIFICATION OF SHORT-
10 AGE.—Section 2812(c) of the Public Health Service Act
11 (42 U.S.C. 300hh–11(c)) is amended by adding at the end
12 the following:

13 “(3) SERVICE BENEFIT.—Individuals appointed
14 to serve under this subsection shall be considered
15 public safety officers under part L of title I of the
16 Omnibus Crime Control and Safe Streets Act of
17 1968. The Secretary shall provide notification to eli-
18 gible individuals of any effect such designation may
19 have on other benefits for which such individuals are
20 eligible, including benefits from private entities.

21 “(4) NOTIFICATION.—Not later than 30 days
22 after the date on which the Secretary determines the
23 number of intermittent disaster-response personnel
24 of the National Disaster Medical System is insuffi-
25 cient to address a public health emergency or poten-

1 tial public health emergency, the Secretary shall sub-
2 mit to the congressional committees of jurisdiction a
3 notification detailing—

4 “(A) the impact such shortage could have
5 on meeting public health needs and emergency
6 medical personnel needs during a public health
7 emergency; and

8 “(B) any identified measures to address
9 such shortage.”.

10 (e) AUTHORIZATION OF APPROPRIATIONS.—Section
11 2812(g) of the Public Health Service Act (42 U.S.C.
12 300hh–11(g)) is amended by striking “\$52,700,000 for
13 each of fiscal years 2014 through 2018” and inserting
14 “\$57,400,000 for each of fiscal years 2019 through
15 2023”.

16 **SEC. 107. VOLUNTEER MEDICAL RESERVE CORPS.**

17 Section 2813 of the Public Health Service Act (42
18 U.S.C. 300hh–15)) is amended—

19 (1) in subsection (a), by amending the second
20 sentence to read as follows: “The Secretary may ap-
21 point a Director to head the Corps and oversee the
22 activities of the Corps chapters that exist at the
23 State, local, and tribal levels.”; and

24 (2) in subsection (i), by striking “\$11,200,000
25 for each of fiscal years 2014 through 2018” and in-

1 serting “\$6,000,000 for each of fiscal years 2019
2 through 2023”.

3 **SEC. 108. CONTINUING THE ROLE OF THE DEPARTMENT OF**
4 **VETERANS AFFAIRS.**

5 Section 8117(g) of title 38, United States Code, is
6 amended by striking “\$155,300,000 for each of fiscal
7 years 2014 through 2018” and inserting “\$126,800,000
8 for each of fiscal years 2019 through 2023”.

9 **SEC. 109. AUTHORIZING THE NATIONAL ADVISORY COM-**
10 **MITTEE ON SENIORS AND DISASTERS.**

11 Subtitle B of title XXVIII of the Public Health Serv-
12 ice Act (42 U.S.C. 300hh et seq.), as amended by section
13 102, is further amended by inserting after section 2811B
14 the following:

15 **“SEC. 2811C. NATIONAL ADVISORY COMMITTEE ON SEN-**
16 **IORS AND DISASTERS.**

17 “(a) ESTABLISHMENT.—The Secretary, in consulta-
18 tion with the Secretary of Homeland Security and the Sec-
19 retary of Veterans Affairs, shall establish an advisory com-
20 mittee to be known as the National Advisory Committee
21 on Seniors and Disasters (referred to in this section as
22 the ‘Advisory Committee’).

23 “(b) DUTIES.—

24 “(1) IN GENERAL.—The Advisory Committee
25 shall—

1 “(A) provide advice and consultation with
2 respect to the activities carried out pursuant to
3 section 2814, as applicable and appropriate;

4 “(B) evaluate and provide input with re-
5 spect to the medical and public health needs of
6 seniors related to the preparation for, response
7 to, and recovery from all-hazards emergencies;
8 and

9 “(C) provide advice and consultation with
10 respect to State emergency preparedness and
11 response activities and seniors, including related
12 drills and exercises pursuant to the prepared-
13 ness goals under section 2802(b).

14 “(2) ADDITIONAL DUTIES.—The Advisory Com-
15 mittee may provide advice and recommendations to
16 the Secretary with respect to seniors and the med-
17 ical and public health grants and cooperative agree-
18 ments as applicable to preparedness and response
19 activities under this title and title III.

20 “(3) MEMBERSHIP.—

21 “(A) IN GENERAL.—The Secretary, in con-
22 sultation with such other heads of agencies as
23 appropriate, shall appoint not more than 25
24 members to the Advisory Committee. In ap-
25 pointing such members, the Secretary shall en-

1 sure that the total membership of the Advisory
2 Committee is an odd number.

3 “(B) REQUIRED MEMBERS.—The members
4 appointed under paragraph (1) shall include—

5 “(i) the Assistant Secretary for Pre-
6 paredness and Response;

7 “(ii) the Director of the Biomedical
8 Advanced Research and Development Au-
9 thority;

10 “(iii) the Director of the Centers for
11 Disease Control and Prevention;

12 “(iv) the Commissioner of Food and
13 Drugs;

14 “(v) the Director of the National In-
15 stitutes of Health;

16 “(vi) the Administrator of the Centers
17 for Medicare & Medicaid Services;

18 “(vii) the Administrator of the Ad-
19 ministration for Community Living;

20 “(viii) the Administrator of the Fed-
21 eral Emergency Management Agency;

22 “(ix) the Under Secretary for Health
23 of the Department of Veterans Affairs;

24 “(x) at least 2 non-Federal health
25 care professionals with expertise in geri-

1 geriatric medical disaster planning, prepared-
2 ness, response, or recovery;

3 “(xi) at least 2 representatives of
4 State, local, territorial, or tribal agencies
5 with expertise in geriatric disaster plan-
6 ning, preparedness, response, or recovery;
7 and

8 “(xii) representatives of such other
9 Federal agencies (such as the Department
10 of Energy and the Department of Home-
11 land Security) as the Secretary determines
12 necessary to fulfill the duties of the Advi-
13 sory Committee.

14 “(c) MEETINGS.—The Advisory Committee shall
15 meet not less frequently than biannually.

16 “(d) ADVISORY COMMITTEE COORDINATION.—

17 “(1) IN GENERAL.—The Secretary shall coordi-
18 nate activities authorized under this section and sec-
19 tions 2811B and 2811D, and make efforts to reduce
20 unnecessary or duplication of meetings, rec-
21 ommendations, and reporting under such sections.
22 Members of the advisory committees under this sec-
23 tion and sections 2811B and 2811D, or their des-
24 ignees, shall meet periodically, and not less than an-
25 nually, to—

1 “(A) review the recommendations devel-
2 oped by such committees to coordinate, as ap-
3 propriate, the implementation of recommenda-
4 tions, in order to reduce gaps, overlap, and du-
5 plication of effort in Federal programs or by
6 Federal grantees; and

7 “(B) align preparedness and response pro-
8 grams or activities to address the overlapping
9 needs of children, individuals with disabilities,
10 and seniors and any challenges in preparing for
11 and responding to such needs.

12 “(2) NOTIFICATION.—The Secretary shall no-
13 tify the congressional committees of jurisdiction
14 upon the convening of each meeting under para-
15 graph (1), and provide minutes from such meeting
16 not later than 90 days after the meeting.

17 “(e) SUNSET.—The Advisory Committee shall termi-
18 nate on September 30, 2023.”.

19 **SEC. 110. NATIONAL ADVISORY COMMITTEE ON INDIVID-**
20 **UALS WITH DISABILITIES AND DISASTERS.**

21 Subtitle B of title XXVIII of the Public Health Serv-
22 ice Act (42 U.S.C. 300hh et seq.), as amended by sections
23 102 and 109, is further amended by inserting after section
24 2811C the following:

1 **“SEC. 2811D. NATIONAL ADVISORY COMMITTEE ON INDI-**
2 **VIDUALS WITH DISABILITIES AND DISAS-**
3 **TERS.**

4 “(a) ESTABLISHMENT.—Not later than 90 days after
5 the date of this section, the Secretary shall establish a na-
6 tional advisory committee to be known as the National Ad-
7 visory Committee on Individuals with Disabilities in All-
8 Hazards Emergencies (referred to in this section as the
9 ‘Advisory Committee’).

10 “(b) DUTIES.—The Advisory Committee shall—

11 “(1) provide advice and consultation with re-
12 spect to activities carried out pursuant to section
13 2814, as applicable and appropriate;

14 “(2) evaluate and provide input with respect to
15 the public health, accessibility, and medical needs of
16 individuals with disabilities as they relate to prepa-
17 ration for, response to, and recovery from public
18 health emergencies; and

19 “(3) provide advice and consultation with re-
20 spect to State emergency preparedness and response
21 activities, including related drills and exercises pur-
22 suant to the preparedness goals under section
23 2802(b).

24 “(c) REPORT.—Not later than February 1, 2020, the
25 Advisory Committee shall submit to the Secretary, the
26 Committee on Energy and Commerce of the House of

1 Representatives, the Committee on Homeland Security of
2 the House of Representatives, the Committee on Veterans'
3 Affairs of the House of Representatives, the Committee
4 on Health, Education, Labor, and Pensions of the Senate,
5 the Committee on Veterans Affairs of the Senate, and the
6 Committee on Homeland Security and Governmental Af-
7 fairs of the Senate a report that evaluates the extent to
8 which individuals with disabilities are thoroughly included
9 in disaster preparedness planning and disaster recovery.
10 Such report shall—

11 “(1) include recommendations that offer spe-
12 cific improvements that could be made across local,
13 State, tribal, territorial, and Federal efforts to im-
14 prove outcomes in areas that include—

15 “(A) preparedness;

16 “(B) planning;

17 “(C) exercises and drills;

18 “(D) alerts, warning, and notifications;

19 “(E) evacuation;

20 “(F) sheltering;

21 “(G) accessing emergency programs and
22 services;

23 “(H) medical care (including mental health
24 care);

25 “(I) temporary housing;

1 “(J) mitigation; and

2 “(K) community resilience; and

3 “(2) assess the strength of existing policies to
4 incorporate such individuals as well as the efficacy
5 of implementation.

6 “(d) COMPOSITION.—

7 “(1) IN GENERAL.—The Secretary, in consulta-
8 tion with such other heads of agencies and depart-
9 ments as may be appropriate, shall appoint not to
10 exceed 25 members to the Advisory Committee.

11 “(2) REQUIRED MEMBERS.—In carrying out
12 paragraph (1), the Secretary shall appoint to the
13 Advisory Committee such individuals as may be ap-
14 propriate to perform the duties described in sub-
15 section (b), which shall include—

16 “(A) the Assistant Secretary for Prepared-
17 ness and Response (or their designee);

18 “(B) the Director of the Administration
19 for Community Living (or their designee);

20 “(C) the Director of the Biomedical Ad-
21 vanced Research and Development Authority
22 (or their designee);

23 “(D) the Director of the Centers for Dis-
24 ease Control and Prevention (or their designee);

1 “(E) the Commissioner of Food and Drugs
2 (or their designee);

3 “(F) the Director of the National Insti-
4 tutes of Health (or their designee);

5 “(G) the Administrator of the Federal
6 Emergency Management Agency (or their des-
7 ignee);

8 “(H) the Director of Office of Disability
9 Integration and Coordination (or their des-
10 ignee);

11 “(I) the Officer for Civil Rights and Civil
12 Liberties of the Department of Homeland Secu-
13 rity (or their designee);

14 “(J) the Chair of the National Council on
15 Disability (or their designee);

16 “(K) the Chair of the United States Access
17 Board (or their designee);

18 “(L) the Director of the Disability Rights
19 Section of the Department of Justice (or their
20 designee);

21 “(M) the Secretary of the Department of
22 Education (or their designee);

23 “(N) the Secretary of the Department of
24 Transportation (or their designee);

1 “(O) the Secretary of the Department of
2 Housing and Urban Development (or their des-
3 ignee);

4 “(P) a representative from the Department
5 of Veterans Affairs Health Administration’s Of-
6 fice of Emergency Management;

7 “(Q) the Director of the Bureau of Prisons
8 (or their designee);

9 “(R) at least four representatives who are
10 individuals with disabilities that have sub-
11 stantive expertise in disability inclusive emer-
12 gency management policy and operations;

13 “(S) at least two non-Federal health care
14 professionals with expertise in disability accessi-
15 bility before, during, and after disasters, med-
16 ical and mass care disaster planning, prepared-
17 ness, response, or recovery; and

18 “(T) at least two representatives from
19 State, local, territorial, or tribal agencies with
20 expertise in disability-inclusive disaster plan-
21 ning, preparedness, response, or recovery.

22 “(e) MEETINGS.—The Advisory Committee shall
23 meet not less than biannually.

24 “(f) DISABILITY DEFINED.—For purposes of this
25 section, the term ‘disability’ has the meaning given such

1 term in section 3 of the Americans with Disabilities Act
2 of 1990.

3 “(g) TERMINATION OF COMMITTEE.—

4 “(1) IN GENERAL.—The Advisory Committee
5 shall terminate on September 30, 2023.

6 “(2) RECOMMENDATION.—Not later than
7 March 30, 2023, the Secretary shall submit to Con-
8 gress a recommendation on whether the Advisory
9 Committee should be extended.”.

10 **SEC. 111. CONSIDERATION FOR AT-RISK INDIVIDUALS.**

11 (a) AT-RISK INDIVIDUALS IN THE NATIONAL
12 HEALTH SECURITY STRATEGY.—Section 2802(b)(4)(B)
13 of the Public Health Service Act (42 U.S.C. 300hh–
14 1(b)(4)(B)) is amended by striking “this section and sec-
15 tions 319C–1, 319F, and 319L” and inserting “this Act”.

16 (b) COUNTERMEASURE CONSIDERATIONS.—Section
17 319L(c)(6) of the Public Health Service Act (42 U.S.C.
18 247d–7e(c)(6)) is amended—

19 (1) by striking “elderly” and inserting “senior
20 citizens”; and

21 (2) by inserting “with relevant characteristics
22 that warrant consideration during the process of re-
23 searching and developing such countermeasures and
24 products” before the period at the end.

1 **SEC. 112. PUBLIC HEALTH SURVEILLANCE.**

2 (a) GOAL.—Section 2802(b) of the Public Health
3 Service Act (42 U.S.C. 300hh–1(b)), as amended by sec-
4 tions 103 and 111, is further amended by adding at the
5 end the following:

6 “(11) PUBLIC HEALTH SURVEILLANCE.—
7 Strengthening the ability of State, tribal, territorial,
8 and local health departments to adapt and expand
9 existing public health surveillance infrastructure to
10 develop a robust national surveillance capacity to
11 capture data on the impact of emerging public
12 health threats. Such capacity shall include emerging
13 threats to pregnant and postpartum women and in-
14 fants, including through monitoring birth defects,
15 developmental disabilities, and other short-term and
16 long-term adverse outcomes.”.

17 (b) ASSURANCE OF CONFIDENTIALITY.—Section
18 308(d) of the Public Health Service Act (42 U.S.C.
19 242m(d)) is amended—

20 (1) by striking “or 307” and inserting “307, or
21 2802(b)(11)”;

22 (2) by striking “or 306” and inserting “306, or
23 2802(b)(11)”.

24 **SEC. 113. GAO STUDY AND REPORT ON DISASTER MEDICAL**
25 **ASSISTANCE TEAMS.**

26 (a) STUDY AND REPORT.—

1 (1) STUDY.—The Comptroller General of the
2 United States shall conduct a study on the mission
3 readiness of disaster medical assistance teams with
4 respect to current and emerging natural and man-
5 made threats.

6 (2) COMPONENTS.—The study conducted pur-
7 suant to paragraph (1) shall include an assessment,
8 in relation to disaster medical assistance teams, of—

9 (A) whether the mission readiness of such
10 teams, and the needs relating to such readiness,
11 have changed over time;

12 (B) the standards the Assistant Secretary
13 for Preparedness and Response of the Depart-
14 ment of Health and Human Services uses to de-
15 termine—

16 (i) the training needs of such teams;

17 and

18 (ii) whether such teams are mission
19 ready;

20 (C) how to improve the determinations de-
21 scribed in subparagraph (B);

22 (D) the extent to which the provision of
23 additional resources (including personnel, train-
24 ing, and equipment) has addressed mission
25 readiness concerns; and

1 (E) the extent to which the Assistant Sec-
2 retary has developed plans to address mission
3 readiness issues.

4 (3) REPORT.—Not later than one year after the
5 date of enactment of this Act, the Comptroller Gen-
6 eral shall submit to the Committee on Energy and
7 Commerce of the House of Representatives and the
8 Committee on Health, Education, Labor, and Pen-
9 sions of the Senate a report containing—

10 (A) the findings of the study conducted
11 pursuant to paragraph (1); and

12 (B) related recommendations.

13 (b) DISASTER MEDICAL ASSISTANCE TEAM DE-
14 FINED.—In this section, the term “disaster medical assist-
15 ance team” means a disaster medical assistance team op-
16 erating pursuant to the National Disaster Medical System
17 established under section 2812 of the Public Health Serv-
18 ice Act (42 U.S.C. 300hh–11).

19 **SEC. 114. MILITARY AND CIVILIAN PARTNERSHIP FOR**
20 **TRAUMA READINESS GRANT PROGRAM.**

21 Title XII of the Public Health Service Act (42 U.S.C.
22 300d et seq.) is amended by adding at the end the fol-
23 lowing new part:

1 **“PART I—MILITARY AND CIVILIAN PARTNERSHIP**
2 **FOR TRAUMA READINESS GRANT PROGRAM**

3 **“SEC. 1291. MILITARY AND CIVILIAN PARTNERSHIP FOR**
4 **TRAUMA READINESS GRANT PROGRAM.**

5 “(a) MILITARY TRAUMA TEAM PLACEMENT PRO-
6 GRAM.—

7 “(1) IN GENERAL.—The Secretary shall award
8 grants to not more than 20 eligible high-acuity trau-
9 ma centers to enable military trauma teams to pro-
10 vide, on a full-time basis, trauma care and related
11 acute care at such trauma centers.

12 “(2) LIMITATIONS.—In the case of a grant
13 awarded under paragraph (1) to an eligible high-
14 acuity trauma center, such grant—

15 “(A) shall be for a period of at least 3
16 years and not more than 5 years (and may be
17 renewed at the end of such period); and

18 “(B) shall be in an amount that does not
19 exceed \$1,000,000 per year.

20 “(3) AVAILABILITY OF FUNDS AFTER PER-
21 FORMANCE PERIOD.—Notwithstanding section 1552
22 of title 31, United States Code, or any other provi-
23 sion of law, funds available to the Secretary for obli-
24 gation for a grant under this subsection shall remain
25 available for expenditure for 100 days after the last
26 day of the performance period of such grant.

1 “(b) MILITARY TRAUMA CARE PROVIDER PLACE-
2 MENT PROGRAM.—

3 “(1) IN GENERAL.—The Secretary shall award
4 grants to eligible trauma centers to enable military
5 trauma care providers to provide trauma care and
6 related acute care at such trauma centers.

7 “(2) LIMITATIONS.—In the case of a grant
8 awarded under paragraph (1) to an eligible trauma
9 center, such grant—

10 “(A) shall be for a period of at least 1 year
11 and not more than 3 years (and may be re-
12 newed at the end of such period); and

13 “(B) shall be in an amount that does not
14 exceed, in a year—

15 “(i) \$100,000 for each military trau-
16 ma care provider that is a physician at
17 such eligible trauma center; and

18 “(ii) \$50,000 for each other military
19 trauma care provider at such eligible trau-
20 ma center.

21 “(c) GRANT REQUIREMENTS.—

22 “(1) DEPLOYMENT.—As a condition of receipt
23 of a grant under this section, a grant recipient shall
24 agree to allow military trauma care providers pro-
25 viding care pursuant to such grant to be deployed by

1 the Secretary of Defense for military operations, for
2 training, or for response to a mass casualty incident
3 or public health emergency.

4 “(2) USE OF FUNDS.—Grants awarded under
5 this section to an eligible trauma center may be used
6 to train and incorporate military trauma care pro-
7 viders into such trauma center, including expendi-
8 tures for malpractice insurance, office space, infor-
9 mation technology, specialty education and super-
10 vision, trauma programs, research, and State license
11 fees for such military trauma care providers.

12 “(d) RULE OF CONSTRUCTION.—Nothing in this sec-
13 tion shall be construed to affect the extent to which State
14 licensing requirements for health care professionals are
15 preempted by other Federal law from applying to military
16 trauma care providers.

17 “(e) REPORTING REQUIREMENTS.—

18 “(1) REPORT TO THE SECRETARY AND THE
19 SECRETARY OF DEFENSE.—Each eligible trauma
20 center or eligible high-acuity trauma center awarded
21 a grant under subsection (a) or (b) for a year shall
22 submit to the Secretary and the Secretary of De-
23 fense a report for such year that includes informa-
24 tion on—

1 “(A) the number and types of trauma
2 cases managed by military trauma teams or
3 military trauma care providers pursuant to such
4 grant during such year;

5 “(B) the financial impact of such grant on
6 the trauma center;

7 “(C) the educational impact on resident
8 trainees in centers where military trauma teams
9 are assigned;

10 “(D) any research conducted during such
11 year supported by such grant; and

12 “(E) any other information required by the
13 Secretaries for the purpose of evaluating the ef-
14 fect of such grant.

15 “(2) REPORT TO CONGRESS.—Not less than
16 once every 2 years, the Secretary, in consultation
17 with the Secretary of Defense, shall submit a report
18 to Congress that includes information on the effect
19 of placing military trauma care providers in trauma
20 centers awarded grants under this section on—

21 “(A) maintaining readiness of military
22 trauma care providers for battlefield injuries;

23 “(B) providing health care to civilian trau-
24 ma patients in both urban and rural settings;

1 “(C) the capability to respond to surges in
2 trauma cases, including as a result of a large
3 scale event; and

4 “(D) the financial state of the trauma cen-
5 ters.

6 “(f) DEFINITIONS.—For purposes of this part:

7 “(1) ELIGIBLE TRAUMA CENTER.—The term
8 ‘eligible trauma center’ means a Level I, II, or III
9 trauma center that satisfies each of the following:

10 “(A) Such trauma center has an agree-
11 ment with the Secretary of Defense to enable
12 military trauma care providers to provide trau-
13 ma care and related acute care at such trauma
14 center.

15 “(B) Such trauma center utilizes a risk-ad-
16 justed benchmarking system to measure per-
17 formance and outcomes, such as the Trauma
18 Quality Improvement Program of the American
19 College of Surgeons.

20 “(C) Such trauma center demonstrates a
21 need for integrated military trauma care pro-
22 viders to maintain or improve the trauma clin-
23 ical capability of such trauma center.

24 “(2) ELIGIBLE HIGH-ACUITY TRAUMA CEN-
25 TER.—The term ‘eligible high-acuity trauma center’

1 means a Level I trauma center that satisfies each of
2 the following:

3 “(A) Such trauma center has an agree-
4 ment with the Secretary of Defense to enable
5 military trauma teams to provide trauma care
6 and related acute care at such trauma center.

7 “(B) At least 20 percent of patients of
8 such trauma center in the most recent 3-month
9 period for which data is available are treated
10 for a major trauma at such trauma center.

11 “(C) Such trauma center utilizes a risk-ad-
12 justed benchmarking system to measure per-
13 formance and outcomes, such as the Trauma
14 Quality Improvement Program of the American
15 College of Surgeons.

16 “(D) Such trauma center is an academic
17 training center—

18 “(i) affiliated with a medical school;

19 “(ii) that maintains residency pro-
20 grams and fellowships in critical trauma
21 specialties and subspecialties, and provides
22 education and supervision of military trau-
23 ma team members according to those spe-
24 cialties and subspecialties; and

1 “(iii) that undertakes research in the
2 prevention and treatment of traumatic in-
3 jury.

4 “(E) Such trauma center serves as a dis-
5 aster response leader for its community, such
6 as by participating in a partnership for State
7 and regional hospital preparedness established
8 under section 319C-2.

9 “(3) MAJOR TRAUMA.—The term ‘major trau-
10 ma’ means an injury that is greater than or equal
11 to 15 on the injury severity score.

12 “(4) MILITARY TRAUMA TEAM.—The term
13 ‘military trauma team’ means a complete military
14 trauma team consisting of military trauma care pro-
15 viders.

16 “(5) MILITARY TRAUMA CARE PROVIDER.—The
17 term ‘military trauma care provider’ means a mem-
18 ber of the Armed Forces who furnishes emergency,
19 critical care, and other trauma acute care, including
20 a physician, military surgeon, physician assistant,
21 nurse, respiratory therapist, flight paramedic, com-
22 bat medic, or enlisted medical technician.

23 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated to carry out this section,

1 \$15,000,000 for each of fiscal years 2019 through 2023,
2 of which—

3 “(1) \$10,000,000 shall be for carrying out sub-
4 section (a); and

5 “(2) \$5,000,000 shall be for carrying out sub-
6 section (b).”.

7 **SEC. 115. IMPROVEMENT OF LOAN REPAYMENT PROGRAM**
8 **FOR PREVENTION ACTIVITIES.**

9 Section 317F of the Public Health Service Act (42
10 U.S.C. Sec. 247b–7) is amended—

11 (1) in subsection (a)(1)—

12 (A) by inserting after “conduct prevention
13 activities” the following: “, including rapid re-
14 sponse to major health threats,”; and

15 (B) by striking “\$35,000” and inserting
16 “\$50,000”;

17 (2) in subsection (a)(2)(B), by striking “3
18 years” and inserting “2 years”; and

19 (3) in subsection (c), by striking “\$500,000”
20 and all that follows through the period at the end
21 and inserting “\$1,000,000 for each of the fiscal
22 years 2019 through 2023.”.

1 **SEC. 116. REPORT ON ADEQUATE NATIONAL BLOOD SUP-**
2 **PLY.**

3 Not later than 1 year after the date of the enactment
4 of this Act, the Secretary of Health and Human Services
5 shall submit to Congress a report containing recommenda-
6 tions related to maintaining an adequate national blood
7 supply, including challenges associated with continuous re-
8 cruitment of blood donors, ensuring adequacy of blood
9 supply in the case of public health emergencies, and imple-
10 mentation of safety measures and innovation.

11 **SEC. 117. GRANTS TO STUDY AND REDUCE HEALTH CARE**
12 **ACQUIRED INFECTIONS.**

13 Part P of title III of the Public Health Service Act
14 (42 U.S.C. 280g et seq.) is amended by adding at the end
15 the following new section:

16 **“SEC. 399V-7. GRANTS TO STUDY AND REDUCE HEALTH**
17 **CARE ACQUIRED INFECTIONS.**

18 “(a) IN GENERAL.—The Secretary shall award
19 grants to eligible entities to study and reduce health care
20 acquired infections that occur in hospital settings.

21 “(b) ELIGIBLE ENTITIES.—To be eligible to receive
22 a grant under subsection (a), an entity shall be a health
23 care system that has—

24 “(1) extensive experience in—

1 “(A) treating patients to full recovery from
2 a high-consequence pathogen such as Ebola;
3 and

4 “(B) teaching and training health care
5 professionals in a health care setting; and

6 “(2) a plan to assess, not later than three years
7 after the date on which the entity receives such a
8 grant, how such grant impacts how health care pro-
9 fessionals are trained and evaluated.

10 “(c) USE OF FUNDS.—Grants awarded under this
11 section to an eligible entity shall be used—

12 “(1) to conduct evidence-based health care re-
13 search on reducing the transmission of health care
14 acquired infections that occur in hospital settings,
15 specifically targeting interprofessional providers, in-
16 cluding nurses, physicians, laboratorians, environ-
17 mental services, food services, facilities, and health
18 care administration; and

19 “(2) to support the four strategic goals of the
20 Department of Health and Human Services relating
21 to—

22 “(A) strengthening health care;

23 “(B) advancing scientific knowledge and
24 innovation;

1 “(C) advancing the health, safety, and
2 well-being of the people of the United States;
3 and

4 “(D) ensuring efficiency, transparency, ac-
5 countability, and effectiveness of programs.

6 “(d) AUTHORIZATION OF APPROPRIATIONS.—For
7 purposes of carrying out this section, there is authorized
8 to be appropriated \$5,000,000 for each of fiscal years
9 2019 through 2023.”.

10 **TITLE II—OPTIMIZING STATE**
11 **AND LOCAL ALL-HAZARDS**
12 **PREPAREDNESS AND RE-**
13 **SPONSE**

14 **SEC. 201. PUBLIC HEALTH EMERGENCIES.**

15 (a) RESPONSE FUND.—Section 319 of the Public
16 Health Service Act (42 U.S.C. 247d) is amended—

17 (1) in subsection (b)—

18 (A) in paragraph (1)—

19 (i) in the first sentence, by inserting
20 before the period the following: “, or if the
21 Secretary determines there is the signifi-
22 cant potential for a public health emer-
23 gency, to allow the Secretary to rapidly re-
24 spond to the immediate needs resulting

1 from such public health emergency or po-
2 tential public health emergency”; and

3 (ii) by inserting after the first sen-
4 tence the following: “The Secretary shall
5 plan for the expedited distribution of
6 amounts in the Fund to appropriate agen-
7 cies and entities.”;

8 (B) by redesignating paragraph (2) as
9 paragraph (3);

10 (C) by inserting after paragraph (1) the
11 following:

12 “(2) USES.—The Secretary may use amounts
13 in the Fund established under paragraph (1)—

14 “(A) to facilitate coordination between and
15 among Federal, State, local, tribal, and terri-
16 torial entities and public and private health
17 care entities that the Secretary determines may
18 be affected by a public health emergency or po-
19 tential public health emergency referred to in
20 paragraph (1) (including communication of
21 such entities with relevant international enti-
22 ties, as applicable);

23 “(B) to make grants, provide for awards,
24 enter into contracts, and conduct supportive in-
25 vestigations pertaining to such a public health

1 emergency or potential public health emergency,
2 including further supporting programs under
3 sections 319C–1 and 319C–2;

4 “(C) to facilitate and accelerate, as appli-
5 cable, advanced research and development of se-
6 curity countermeasures (as defined in section
7 319F–2), qualified countermeasures (as defined
8 in section 319F–1), or qualified pandemic or
9 epidemic products (as defined in section 319F–
10 3), that are applicable to such a public health
11 emergency or potential public health emergency;

12 “(D) to strengthen biosurveillance capabili-
13 ties and laboratory capacity to identify, collect,
14 and analyze information regarding such a pub-
15 lic health emergency or potential public health
16 emergency, including the systems under section
17 319D;

18 “(E) to support initial emergency oper-
19 ations and assets related to preparation and de-
20 ployment of intermittent disaster-response per-
21 sonnel under section 2812, and the Medical Re-
22 serve Corps under section 2813; and

23 “(F) to carry out other activities, as the
24 Secretary determines applicable and appro-
25 priate.”; and

1 (D) by inserting after paragraph (3), as so
2 redesignated, the following:

3 “(4) REVIEW.—Not later than 2 years after the
4 date of enactment of the Pandemic and All-Hazards
5 Preparedness and Advancing Innovation Act of
6 2018, the Secretary, in coordination with the Assist-
7 ant Secretary for Preparedness and Response, shall
8 conduct a review of the Fund under this subsection,
9 and provide recommendations to the Committee on
10 Health, Education, Labor, and Pensions and the
11 Committee on Appropriations of the Senate and the
12 Committee on Energy and Commerce and the Com-
13 mittee on Appropriations of the House of Represent-
14 atives on policies to improve such Fund for the uses
15 described in paragraph (2).

16 “(5) GAO REVIEW AND REPORT.—The Comp-
17 troller General of the United States shall conduct a
18 review of the Fund under this subsection, including
19 the uses and the resources available in the Fund.
20 Not later than 4 years after the date of enactment
21 of the Pandemic and All-Hazards Preparedness and
22 Advancing Innovation Act of 2018, the Comptroller
23 General shall submit to the Committee on Energy
24 and Commerce of the House of Representatives and
25 the Committee on Health, Education, Labor, and

1 Pensions of the Senate a report on such review, in-
2 cluding recommendations related to such review.”;
3 and

4 (2) in subsection (c), by striking “section.” and
5 inserting “section or funds otherwise provided for
6 emergency response.”.

7 (b) TEMPORARY REASSIGNMENT OF FEDERALLY
8 FUNDED PERSONNEL.—Section 319(e)(8) of the Public
9 Health Service Act (42 U.S.C. 247d(e)(8)) is amended by
10 striking “2018” and inserting “2023”.

11 **SEC. 202. IMPROVING STATE AND LOCAL PUBLIC HEALTH**
12 **SECURITY.**

13 (a) IN GENERAL.—Section 319C–1 of the Public
14 Health Service Act (42 U.S.C. 247d–3a) is amended—

15 (1) in subsection (a), by inserting “, acting
16 through the Director of the Centers for Disease
17 Control and Prevention,” after “the Secretary”;

18 (2) in subsection (b)(2)(A)—

19 (A) in clause (vi), by inserting “, including
20 public health agencies with specific expertise
21 that may be relevant to public health security,
22 such as environmental health agencies,” after
23 “stakeholders”;

24 (B) in clause (viii), by striking at the end
25 “and”;

1 (C) in clause (ix), by adding at the end
2 “and”; and

3 (D) by inserting after clause (ix) the fol-
4 lowing new clause:

5 “(x) a description of—

6 “(I) the measures the entity will
7 have in place to prioritize nursing fa-
8 cilities and skilled nursing facilities
9 with respect to public health emer-
10 gency preparedness in the same man-
11 ner as such plan will prioritize hos-
12 pitals, while ensuring that, in
13 prioritizing nursing facilities, skilled
14 nursing facilities, and hospitals, the
15 entity will retain the discretion to
16 prioritize among such facilities; and

17 “(II) the plans that utility com-
18 panies within the entity’s jurisdiction
19 have in place to ensure that utilities
20 will remain functioning or return to
21 functioning as soon as practicable
22 during outages caused by natural or
23 manmade disasters;”;

24 (3) in subsection (e), by striking “, and local
25 emergency plans.” and inserting “, local emergency

1 plans, and any regional health care emergency pre-
2 paredness and response system established pursuant
3 to the applicable guidelines under section 319C–3.”;
4 and

5 (4) in subsection (h)(1)(A), by striking
6 “\$641,900,000 for fiscal year 2014 for awards pur-
7 suant to paragraph (3) (subject to the authority of
8 the Secretary to make awards pursuant to para-
9 graphs (4) and (5)), and \$641,900,000 for each of
10 fiscal years 2015 through 2018” and inserting
11 “\$670,000,000 for each of fiscal years 2019 through
12 2023”.

13 (b) EXCEPTION RELATING TO APPLICATION OF CER-
14 TAIN REQUIREMENTS.—Section 319C–1(g) of the Public
15 Health Service Act (42 U.S.C. 247d–3a(g)) is amended—

16 (1) in paragraph (5)—

17 (A) by striking “Beginning with fiscal year
18 2009” and inserting “Beginning with fiscal
19 year 2019”;

20 (B) by striking “for the immediately pre-
21 ceding fiscal year” and inserting “for either of
22 the two immediately preceding fiscal years”;
23 and

24 (C) by striking “2008” and inserting
25 “2019”; and

1 (2) by amending subparagraph (A) of para-
2 graph (6) to read as follows:

3 “(A) IN GENERAL.—The amounts de-
4 scribed in this paragraph are the following
5 amounts that are payable to an entity for ac-
6 tivities described in section 319C–1 or 319C–2:

7 “(i) For each of the first two fiscal
8 years immediately following a fiscal year in
9 which an entity experienced a failure de-
10 scribed in subparagraph (A) or (B) of
11 paragraph (5) by the entity, an amount
12 equal to 10 percent of the amount the enti-
13 ty was eligible to receive for each such fis-
14 cal year.

15 “(ii) For each of the first two fiscal
16 years immediately following two consecu-
17 tive fiscal years in which an entity experi-
18 enced such a failure, an amount equal to
19 15 percent of the amount the entity was el-
20 igible to receive for each of such first two
21 fiscal years, disregarding any withholding
22 of funds that would have been made in
23 each such year by virtue of clause (i). The
24 amount determined pursuant to the pre-
25 vious sentence shall be in lieu of any

1 amount that would have been withheld for
2 each such year by virtue of clause (i).

3 “(iii) For each of the first two fiscal
4 years immediately following three consecu-
5 tive fiscal years in which an entity experi-
6 enced such a failure, an amount equal to
7 20 percent of the amount the entity was el-
8 igible to receive for each of such first two
9 fiscal years, disregarding any withholding
10 of funds that would have been made in
11 each such year by virtue of clauses (i) and
12 (ii). The amount determined pursuant to
13 the previous sentence shall be in lieu of
14 any amount that would have been withheld
15 for each such year by virtue of clauses (i)
16 and (ii).

17 “(iv) For each of the first two fiscal
18 years immediately following four consecu-
19 tive fiscal years in which an entity experi-
20 enced such a failure, an amount equal to
21 25 percent of the amount the entity was el-
22 igible to receive for each of such first two
23 fiscal years, disregarding any withholding
24 of funds that would have been made in
25 each such year by virtue of clauses (i), (ii),

1 and (iii). The amount determined pursuant
2 to the previous sentence shall be in lieu of
3 any amount that would have been withheld
4 for each such year by virtue of clauses (i),
5 (ii), and (iii).”.

6 (c) EFFECTIVE DATE.—The amendments made by
7 subsection (a) shall take effect on the date of enactment
8 of this Act and apply with respect to cooperative agree-
9 ments awarded on or after such date of enactment.

10 **SEC. 203. STRENGTHENING THE HOSPITAL PREPAREDNESS**
11 **PROGRAM.**

12 Section 319C–2 of the Public Health Service Act (42
13 U.S.C. 247d–3b) is amended—

14 (1) by amending the section heading to read as
15 follows: “**STATE AND REGIONAL HEALTH CARE**
16 **PREPAREDNESS AND RESPONSE TO IMPROVE**
17 **SURGE CAPACITY**”;

18 (2) in subsection (a), by striking “hospital pre-
19 paredness for” and inserting “health care prepared-
20 ness for and response to”;

21 (3) in subsection (b)(1)(A)—

22 (A) in the matter preceding clause (i)—

23 (i) by striking “partnership” and in-
24 serting “coalition”; and

- 1 (ii) by striking “consisting of” and in-
2 serting “that includes”;
3 (B) in clause (ii), by striking “and” at the
4 end;
5 (C) in clause (iii)(III), by striking “and”
6 at the end; and
7 (D) by adding at the end the following:
8 “(iv) an emergency medical service or-
9 ganization; and
10 “(v) an emergency management orga-
11 nization; and”;
12 (4) in subsection (c), by inserting after “pre-
13 paredness” the following: “and response”;
14 (5) in subsection (d)—
15 (A) in paragraph (1)(A)—
16 (i) in clause (i), by striking “; and”
17 and inserting a semicolon;
18 (ii) by redesignating clause (ii) as
19 clause (iii); and
20 (iii) by inserting after clause (i) the
21 following:
22 “(ii) among one or more facilities in a
23 regional health care emergency system
24 under section 319C–3; and”;

1 (B) in paragraph (1)(B), by striking
2 “partnership” each place it appears and insert-
3 ing “coalition”; and

4 (C) in paragraph (2)(C), by striking “med-
5 ical preparedness” and inserting “preparedness
6 and response”;

7 (6) in subsection (f), by striking “partnership”
8 and inserting “coalition”;

9 (7) in subsection (g)(2)—

10 (A) by striking “Partnerships” and insert-
11 ing “Coalitions”;

12 (B) by striking “partnerships” and insert-
13 ing “coalitions”; and

14 (C) by inserting after “preparedness” the
15 following: “and response”;

16 (8) in subsection (i)(1)—

17 (A) by striking “An entity” and inserting
18 “A coalition”;

19 (B) by striking “such partnership” and in-
20 serting “such coalition”; and

21 (C) by adding at the end the following: “In
22 submitting reports pursuant to this paragraph,
23 an entity shall include information on the
24 progress (if any) that the entity has made to-
25 wards the implementation of section 319C–3.”;

1 (9) in subsection (j)(1), by striking
2 “\$374,700,000 for each of fiscal years 2014 through
3 2018” and inserting “\$264,600,000 for each of fis-
4 cal years 2019 through 2023”; and

5 (10) in subsection (j)(2), in the paragraph
6 heading, by striking “PARTNERSHIPS” and inserting
7 “COALITIONS”.

8 **SEC. 204. IMPROVING BENCHMARKS AND STANDARDS FOR**
9 **PREPAREDNESS AND RESPONSE.**

10 (a) EVALUATING MEASURABLE EVIDENCE-BASED
11 BENCHMARKS AND OBJECTIVE STANDARDS.—Section
12 319C–1 of the Public Health Service Act (42 U.S.C.
13 247d–3a) is amended by inserting after subsection (j) the
14 following:

15 “(k) EVALUATION.—

16 “(1) IN GENERAL.—Not later than 2 years
17 after the date of enactment of the Pandemic and
18 All-Hazards Preparedness and Advancing Innovation
19 Act of 2018 and every 2 years thereafter, the Sec-
20 retary shall conduct an evaluation of the evidence-
21 based benchmarks and objective standards required
22 under subsection (g). Such evaluation shall be sub-
23 mitted to the congressional committees of jurisdic-
24 tion together with the National Health Security

1 Strategy under section 2802, at such time as such
2 strategy is submitted.

3 “(2) CONTENT.—The evaluation under this
4 paragraph shall include—

5 “(A) a review of evidence-based bench-
6 marks and objective standards, and associated
7 metrics and targets;

8 “(B) a discussion of changes to any evi-
9 dence-based benchmarks and objective stand-
10 ards, and the effect of such changes on the abil-
11 ity to track whether entities are meeting or
12 making progress toward the goals under this
13 section and, to the extent practicable, the appli-
14 cable goals of the National Health Security
15 Strategy under section 2802;

16 “(C) a description of amounts received by
17 eligible entities, as described in subsection (b)
18 and section 319C–2(b), and amounts received
19 by subrecipients and the effect of such funding
20 on meeting evidence-based benchmarks and ob-
21 jective standards; and

22 “(D) recommendations, as applicable and
23 appropriate, to improve evidence-based bench-
24 marks and objective standards to more accu-
25 rately assess the ability of entities receiving

1 awards under this section to better achieve the
2 goals under this section and section 2802.”.

3 (b) EVALUATING THE PARTNERSHIP FOR STATE AND
4 REGIONAL HOSPITAL PREPAREDNESS.—Section 319C–
5 2(i)(1) (42 U.S.C. 247–3b(i)(1)), as amended by section
6 203, is further amended by striking “section 319C–1(g),
7 (i), and (j)” and inserting “section 319C–1(g), (i), (j), and
8 (k)”.

9 **SEC. 205. PUBLIC HEALTH AND HEALTH CARE SYSTEM SIT-**
10 **UATIONAL AWARENESS AND BIOSURVEIL-**
11 **LANCE CAPABILITIES.**

12 (a) FACILITIES, CAPACITIES, AND BIOSURVEILLANCE
13 CAPABILITIES.—Section 319D of the Public Health Serv-
14 ice Act (42 U.S.C. 247d–4) is amended—

15 (1) in the section heading, by striking “**REVI-**
16 **TALIZING**” and inserting “**FACILITIES AND CA-**
17 **PACITIES OF**”;

18 (2) in subsection (a)—

19 (A) in the subsection heading, by striking
20 “FACILITIES; CAPACITIES” and inserting “IN
21 GENERAL”;

22 (B) in paragraph (1), by striking “and im-
23 proved” and inserting “, improved, and appro-
24 priately maintained”;

1 (C) in paragraph (3), in the matter pre-
2 ceding subparagraph (A), by striking “expand,
3 enhance, and improve” and inserting “expand,
4 improve, enhance, and appropriately maintain”;
5 and

6 (D) by adding at the end the following:

7 “(4) STUDY OF RESOURCES FOR FACILITIES
8 AND CAPACITIES.—Not later than June 1, 2022, the
9 Comptroller General of the United States shall con-
10 duct a study on Federal spending in fiscal years
11 2013 through 2018 for activities authorized under
12 this subsection. Such study shall include a review
13 and assessment of obligations and expenditures di-
14 rectly related to each activity under paragraphs (2)
15 and (3), including a specific accounting of, and de-
16 lineation between, obligations and expenditures in-
17 curred for the construction, renovation, equipping,
18 and security upgrades of facilities and associated
19 contracts under this subsection, and the obligations
20 and expenditures incurred to establish and improve
21 the situational awareness and biosurveillance net-
22 work under subsection (b), and shall identify the
23 agency or agencies incurring such obligations and
24 expenditures.”;

25 (3) in subsection (b)—

1 (A) in the subsection heading, by striking
2 “NATIONAL” and inserting “ESTABLISHMENT
3 OF SYSTEMS OF PUBLIC HEALTH ”;

4 (B) in paragraph (1)(B), by inserting “im-
5 munization information systems,” after “cen-
6 ters,”; and

7 (C) in paragraph (2)—

8 (i) by inserting “develop a plan to,
9 and” after “The Secretary shall”; and

10 (ii) by inserting “and in a form read-
11 ily usable for analytical approaches” after
12 “in a secure manner”; and

13 (D) by amending paragraph (3) to read as
14 follows:

15 “(3) STANDARDS.—

16 “(A) IN GENERAL.—Not later than 1 year
17 after the date of the enactment of the Pan-
18 demic and All-Hazards Preparedness and Ad-
19 vancing Innovation Act of 2018, the Secretary,
20 in cooperation with health care providers, State,
21 local, tribal, and territorial public health offi-
22 cials, and relevant Federal agencies (including
23 the Office of the National Coordinator for
24 Health Information Technology and the Na-
25 tional Institute of Standards and Technology),

1 shall, as necessary, adopt technical and report-
2 ing standards, including standards for inter-
3 operability as defined by section 3000, for net-
4 works under paragraph (1) and update such
5 standards as necessary. Such standards shall be
6 made available on the internet website of the
7 Department of Health and Human Services, in
8 a manner that does not compromise national se-
9 curity.

10 “(B) DEFERENCE TO STANDARDS DEVEL-
11 OPMENT ORGANIZATIONS.—In adopting and im-
12 plementing standards under this subsection and
13 subsection (c), the Secretary shall give def-
14 erence to standards published by standards de-
15 velopment organizations and voluntary con-
16 sensus-based standards entities.”;

17 (4) in subsection (c)—

18 (A) in paragraph (1)—

19 (i) by striking “Not later than 2 years
20 after the date of enactment of the Pan-
21 demic and All-Hazards Preparedness Re-
22 authorization Act of 2013, the Secretary”
23 and inserting “The Secretary”;

1 (ii) by inserting “, and improve as ap-
2 plicable and appropriate,” after “shall es-
3 tablish”;

4 (iii) by striking “of rapid” and insert-
5 ing “of, rapid”; and

6 (iv) by striking “such connectivity”
7 and inserting “such interoperability”;

8 (B) by amending paragraph (2) to read as
9 follows:

10 “(2) COORDINATION AND CONSULTATION.—In
11 establishing and improving the network under para-
12 graph (1) the Secretary shall—

13 “(A) facilitate coordination among agencies
14 within the Department of Health and Human
15 Services that provide, or have the potential to
16 provide, information and data to, and analyses
17 for, the situational awareness and biosurveil-
18 lance network under paragraph (1), including
19 coordination among relevant agencies related to
20 health care services, the facilitation of health
21 information exchange (including the Office of
22 the National Coordinator for Health Informa-
23 tion Technology), and public health emergency
24 preparedness and response; and

1 “(B) consult with the Secretary of Agri-
2 culture, the Secretary of Commerce (and the
3 Director of the National Institute of Standards
4 and Technology), the Secretary of Defense, the
5 Secretary of Homeland Security, and the Sec-
6 retary of Veterans Affairs, and the heads of
7 other Federal agencies, as the Secretary deter-
8 mines appropriate.”;

9 (C) in paragraph (3)—

10 (i) by redesignating subparagraphs
11 (A) through (E) as clauses (i) through (v),
12 respectively, and adjusting the margins ac-
13 cordingly;

14 (ii) in clause (iv), as so redesign-
15 nated—

16 (I) by inserting “immunization
17 information systems,” after “poison
18 control,”; and

19 (II) by striking “ and clinical
20 laboratories” and inserting “, clinical
21 laboratories, and public environmental
22 health agencies”;

23 (iii) by striking “The network” and
24 inserting the following:

25 “(A) IN GENERAL.—The network”; and

1 (iv) by adding at the end the fol-
2 lowing:

3 “(B) REVIEW.—Not later than 2 years
4 after the date of the enactment of the Pan-
5 demic and All-Hazards Preparedness and Ad-
6 vancing Innovation Act of 2018 and every 6
7 years thereafter, the Secretary shall conduct a
8 review of the elements described in subpara-
9 graph (A). Such review shall include a discus-
10 sion of the addition of any elements pursuant to
11 clause (v), including elements added to advanc-
12 ing new technologies, and identify any chal-
13 lenges in the incorporation of elements under
14 subparagraph (A). The Secretary shall provide
15 such review to the congressional committees of
16 jurisdiction.”;

17 (D) in paragraph (5)—

18 (i) by redesignating subparagraphs
19 (A) through (D) as clauses (i) through
20 (iv), respectively, and adjusting the mar-
21 gins accordingly;

22 (ii) by striking “In establishing” and
23 inserting the following:

24 “(A) IN GENERAL.—In establishing”;

1 (iii) by adding at the end the fol-
2 lowing:

3 “(B) PUBLIC MEETING.—

4 “(i) IN GENERAL.—Not later than
5 180 days after the date of enactment of
6 the Pandemic and All-Hazards Prepared-
7 ness and Advancing Innovation Act of
8 2018, the Secretary shall convene a public
9 meeting for purposes of discussing and
10 providing input on the potential goals,
11 functions, and uses of the network de-
12 scribed in paragraph (1) and incorporating
13 the elements described in paragraph
14 (3)(A).

15 “(ii) EXPERTS.—The public meeting
16 shall include representatives of relevant
17 Federal agencies (including representatives
18 from the Office of the National Coordi-
19 nator for Health Information Technology
20 and the National Institute of Standards
21 and Technology); State, local, tribal, and
22 territorial public health officials; stake-
23 holders with expertise in biosurveillance
24 and situational awareness; stakeholders
25 with expertise in capabilities relevant to

1 biosurveillance and situational awareness,
2 such as experts in informatics and data
3 analytics (including experts in prediction,
4 modeling, or forecasting); and other rep-
5 resentatives as the Secretary determines
6 appropriate.

7 “(iii) TOPICS.—Such public meeting
8 shall include a discussion of—

9 “(I) data elements, including
10 minimal or essential data elements,
11 that are voluntarily provided for such
12 network, which may include elements
13 from public health and public and pri-
14 vate health care entities, to the extent
15 practicable;

16 “(II) standards and implementa-
17 tion specifications that may improve
18 the collection, analysis, and interpre-
19 tation of data during a public health
20 emergency;

21 “(III) strategies to encourage the
22 access, exchange, and use of informa-
23 tion;

24 “(IV) considerations for State,
25 local, tribal, and territorial capabilities

1 and infrastructure related to data ex-
2 change and interoperability;

3 “(V) privacy and security protec-
4 tions provided at the Federal, State,
5 local, tribal, and territorial levels, and
6 by nongovernmental stakeholders; and

7 “(VI) opportunities for the incor-
8 poration of innovative technologies to
9 improve the network.”; and

10 (iv) in subparagraph (A), as so des-
11 ignated by clause (ii)—

12 (I) in clause (i), as so redesign-
13 nated—

14 (aa) by striking “as deter-
15 mined” and inserting “as adopt-
16 ed”; and

17 (bb) by inserting “and the
18 National Institute of Standards
19 and Technology” after “Office of
20 the National Coordinator for
21 Health Information Technology”;

22 (II) in clause (iii), as so redesign-
23 nated, by striking “; and” and insert-
24 ing a semicolon;

1 (III) in clause (iv), as so redesign-
2 nated, by striking the period and in-
3 serting “; and”; and

4 (IV) by adding at the end the fol-
5 lowing:

6 “(v) pilot test standards and imple-
7 mentation specifications, consistent with
8 the process described in section
9 3002(b)(3)(C), which State, local, tribal,
10 and territorial public health entities may
11 utilize, on a voluntary basis, as a part of
12 the network.”;

13 (E) by redesignating paragraph (6) as
14 paragraph (7);

15 (F) by inserting after paragraph (5) the
16 following:

17 “(6) STRATEGY AND IMPLEMENTATION
18 PLAN.—

19 “(A) IN GENERAL.—Not later than 18
20 months after the date of enactment of the Pan-
21 demic and All-Hazards Preparedness and Ad-
22 vancing Innovation Act of 2018, the Secretary
23 shall submit to the congressional committees of
24 jurisdiction a coordinated strategy and an ac-
25 companying implementation plan that—

1 “(i) is informed by the public meeting
2 under paragraph (5)(B);

3 “(ii) includes a review and assessment
4 of existing capabilities of the network and
5 related infrastructure, including input pro-
6 vided by the public meeting under para-
7 graph (5)(B);

8 “(iii) identifies and demonstrates the
9 measurable steps the Secretary will carry
10 out to—

11 “(I) develop, implement, and
12 evaluate the network described in
13 paragraph (1), utilizing elements de-
14 scribed in paragraph (3)(A);

15 “(II) modernize and enhance bio-
16 surveillance activities, including strat-
17 egies to include innovative tech-
18 nologies and analytical approaches
19 (including prediction and forecasting
20 for pandemics and all-hazards) from
21 public and private entities;

22 “(III) improve information shar-
23 ing, coordination, and communication
24 among disparate biosurveillance sys-
25 tems supported by the Department of

1 Health and Human Services, includ-
2 ing the identification of methods to
3 improve accountability, better utilize
4 resources and workforce capabilities,
5 and incorporate innovative tech-
6 nologies within and across agencies;
7 and

8 “(IV) test and evaluate capabili-
9 ties of the interoperable network of
10 systems to improve situational aware-
11 ness and biosurveillance capabilities;

12 “(iv) includes performance measures
13 and the metrics by which performance
14 measures will be assessed with respect to
15 the measurable steps under clause (iii);
16 and

17 “(v) establishes dates by which each
18 measurable step under clause (iii) will be
19 implemented.”.

20 “(B) ANNUAL BUDGET PLAN.—Not later
21 than 2 years after the date of enactment of the
22 Pandemic and All-Hazards Preparedness and
23 Advancing Innovation Act of 2018 and on an
24 annual basis thereafter, in accordance with the
25 strategy and implementation plan under this

1 paragraph, the Secretary shall, taking into ac-
2 count recommendations provided by the Na-
3 tional Biodefense Science Board, develop a
4 budget plan based on the strategy and imple-
5 mentation plan under this section. Such budget
6 plan shall include—

7 “(i) a summary of resources pre-
8 viously expended to establish, improve, and
9 utilize the nationwide public health situa-
10 tional awareness and biosurveillance net-
11 work under paragraph (1);

12 “(ii) estimates of costs and resources
13 needed to establish and improve the net-
14 work under paragraph (1) according to the
15 strategy and implementation plan under
16 subparagraph (A);

17 “(iii) the identification of gaps and in-
18 efficiencies in nationwide public health sit-
19 uational awareness and biosurveillance ca-
20 pabilities, resources, and authorities need-
21 ed to address such gaps; and

22 “(iv) a strategy to minimize and ad-
23 dress such gaps and improve inefficien-
24 cies.”;

25 (G) in paragraph (7), as so redesignated—

1 (i) in subparagraph (A), by inserting
2 “(taking into account zoonotic disease, in-
3 cluding gaps in scientific understanding of
4 the interactions between human, animal,
5 and environmental health)” after “human
6 health”;

7 (ii) in subparagraph (B)—

8 (I) by inserting “and gaps in sur-
9 veillance programs” after “surveil-
10 lance programs”; and

11 (II) by striking “; and” and in-
12 serting a semicolon;

13 (iii) in subparagraph (C)—

14 (I) by inserting “, animal health
15 organizations related to zoonotic dis-
16 ease,” after “health care entities”;
17 and

18 (II) by striking the period and
19 inserting “; and”; and

20 (iv) by adding at the end the fol-
21 lowing:

22 “(D) provide recommendations to the Sec-
23 retary on policies and procedures to complete
24 the steps described in this paragraph in a man-
25 ner that is consistent with section 2802.”; and

1 (H) by adding at the end the following:

2 “(8) SITUATIONAL AWARENESS AND BIO-
3 SURVEILLANCE AS A NATIONAL SECURITY PRI-
4 ORITY.—The Secretary, on a periodic basis as appli-
5 cable and appropriate, shall meet with the Director
6 of National Intelligence to inform the development
7 and capabilities of the nationwide public health situ-
8 ational awareness and biosurveillance network.”;

9 (5) in subsection (d)—

10 (A) in paragraph (1)—

11 (i) by inserting “environmental health
12 agencies,” after “public health agencies,”;
13 and

14 (ii) by inserting “immunization pro-
15 grams,” after “poison control centers,”;
16 and

17 (B) in paragraph (2)—

18 (i) in subparagraph (B), by striking
19 “and” at the end;

20 (ii) in subparagraph (C), by striking
21 the period and inserting “; and”; and

22 (iii) by adding after subparagraph (C)
23 the following:

1 “(D) an implementation plan that may in-
2 clude measurable steps to achieve the purposes
3 described in paragraph (1).”; and

4 (C) by striking paragraph (5) and insert-
5 ing the following:

6 “(5) TECHNICAL ASSISTANCE.—The Secretary
7 may provide technical assistance to States, localities,
8 tribes, and territories or a consortium of States, lo-
9 calities, tribes, and territories receiving an award
10 under this subsection regarding interoperability and
11 the technical standards set forth by the Secretary.”;

12 (6) by redesignating subsections (f) and (g) as
13 subsections (i) and (j), respectively; and

14 (7) by inserting after subsection (e) the fol-
15 lowing:

16 “(f) PERSONNEL AUTHORITIES.—

17 “(1) SPECIALLY QUALIFIED PERSONNEL.—In
18 addition to any other personnel authorities, to carry
19 out subsection (b) and subsection (c), the Secretary
20 may—

21 “(A) appoint highly qualified individuals to
22 scientific or professional positions at the Cen-
23 ters for Disease Control and Prevention, not to
24 exceed 30 such employees at any time (specific
25 to positions authorized by this subsection), with

1 expertise in capabilities relevant to biosurveil-
2 lance and situational awareness, such as experts
3 in informatics and data analytics (including ex-
4 perts in prediction, modeling, or forecasting),
5 and other related scientific or technical fields;
6 and

7 “(B) compensate individuals appointed
8 under subparagraph (A) in the same manner
9 and subject to the same terms and conditions in
10 which individuals appointed under 9903 of title
11 5, United States Code, are compensated, with-
12 out regard to the provisions of chapter 51 and
13 subchapter III of chapter 53 of that title relat-
14 ing to classification and General Schedule pay
15 rates.

16 “(2) LIMITATIONS.—The Secretary shall exer-
17 cise the authority under paragraph (1) in a manner
18 that is consistent with the limitations described in
19 section 319F–1(e)(2).

20 “(g) TIMELINE.—The Secretary shall accomplish the
21 purposes under subsections (b) and (c) no later than Sep-
22 tember 30, 2023, and shall provide a justification to the
23 congressional committees of jurisdiction for any missed or
24 delayed implementation of measurable steps identified
25 under subsection (c)(6)(A)(iii).

1 “(h) INDEPENDENT EVALUATION.—Not later than 3
2 years after the date of enactment of the Pandemic and
3 All-Hazards Preparedness and Advancing Innovation Act
4 of 2018, the Comptroller General of the United States
5 shall conduct an independent evaluation, and submit to
6 the Secretary and the congressional committees of juris-
7 diction a report concerning the activities conducted under
8 subsections (b) and (c), and provide recommendations, as
9 applicable and appropriate, on necessary improvements to
10 the biosurveillance and situational awareness network.”.

11 (b) AUTHORIZATION OF APPROPRIATIONS.—Sub-
12 section (i) of section 319D of the Public Health Service
13 Act (42 U.S.C. 247d–4), as redesignated by subsection
14 (a)(6), is amended by striking “\$138,300,000 for each of
15 fiscal years 2014 through 2018” and inserting
16 “\$161,800,000 for each of fiscal years 2019 through
17 2023”.

18 **SEC. 206. AUTHORIZATION OF APPROPRIATIONS FOR**
19 **EMERGENCY SYSTEM FOR ADVANCED REG-**
20 **ISTRATION OF VOLUNTEER HEALTH PROFES-**
21 **SIONALS.**

22 Section 319I(k) of the Public Health Service Act (42
23 U.S.C. 247d–7b(k)) is amended by striking “fiscal years
24 2014 through 2018” and inserting “fiscal years 2019
25 through 2023”.

1 **SEC. 207. REGIONAL HEALTH CARE EMERGENCY PRE-**
2 **PAREDNESS AND RESPONSE SYSTEMS.**

3 Part B of title III of the Public Health Service Act
4 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
5 tion 319C–2 the following new section:

6 **“SEC. 319C–3. GUIDELINES FOR REGIONAL HEALTH CARE**
7 **EMERGENCY PREPAREDNESS AND RESPONSE**
8 **SYSTEMS.**

9 “(a) PURPOSE.—It is the purpose of this section to
10 identify and provide guidelines for regional systems of hos-
11 pitals, health care facilities, and other public and private
12 sector entities, with varying levels of capability to treat
13 patients and increase medical surge capacity during, in ad-
14 vance of, and immediately following a public health emer-
15 gency, including threats posed by one or more chemical,
16 biological, radiological, and nuclear agents, including
17 emerging infectious diseases.

18 “(b) GUIDELINES.—The Assistant Secretary for Pre-
19 paredness and Response, in consultation with the Director
20 of the Centers for Disease Control and Prevention, the Ad-
21 ministrator of the Centers for Medicare & Medicaid Serv-
22 ices, the Administrator of the Health Resources and Serv-
23 ices Administration, the Commissioner of Food and
24 Drugs, the Assistant Secretary for Mental Health and
25 Substance Use, the Assistant Secretary of Labor for Occu-
26 pational Safety and Health, the Secretary of Veterans Af-

1 fairs, the heads of such other Federal agencies as the Sec-
2 retary determines to be appropriate, and State, local, trib-
3 al, and territorial public health officials, shall, not later
4 than 2 years after the date of enactment of this section—

5 “(1) identify and develop a set of guidelines re-
6 lating to practices and protocols for all-hazards pub-
7 lic health emergency preparedness and response for
8 hospitals and health care facilities to provide appro-
9 priate patient care during, in advance of, or imme-
10 diately following, a public health emergency, result-
11 ing from one or more chemical, biological, radio-
12 logical, or nuclear agents, including emerging infec-
13 tious diseases (which may include existing practices,
14 such as trauma care and medical surge capacity and
15 capabilities), with respect to—

16 “(A) a regional approach to identifying
17 hospitals and health care facilities based on
18 varying capabilities and capacity to treat pa-
19 tients affected by such emergency, including—

20 “(i) the manner in which the system
21 will coordinate with and integrate the
22 health care coalitions and entities de-
23 scribed in section 319C–2(b); and

24 “(ii) informing and educating appro-
25 priate first responders and health care sup-

1 ply chain partners of the regional emer-
2 gency preparedness and response capabili-
3 ties and medical surge capacity of such
4 hospitals and health care facilities in the
5 community;

6 “(B) physical and technological infrastruc-
7 ture, laboratory capacity, staffing, blood supply,
8 and other supply chain needs, taking into ac-
9 count resiliency, geographic considerations, and
10 rural considerations;

11 “(C) protocols or best practices for the
12 safety and personal protection of workers who
13 handle human remains and health care workers
14 (including with respect to protective equipment
15 and supplies, waste management processes, and
16 decontamination), sharing of specialized experi-
17 ence among the health care workforce, behav-
18 ioral health, psychological resilience, and train-
19 ing of the workforce, as applicable;

20 “(D) in a manner that allows for disease
21 containment (within the meaning of section
22 2802(b)(2)(B)), coordinated medical triage,
23 treatment, and transportation of patients, based
24 on patient medical need (including patients in
25 rural areas), to the appropriate hospitals or

1 health care facilities within the regional system
2 or, as applicable and appropriate, between sys-
3 tems in different States or regions; and

4 “(E) the needs of children and other at-
5 risk individuals;

6 “(2) make such guidelines available on the pub-
7 lic website of the Department of Health and Human
8 Services in a manner that does not compromise na-
9 tional security; and

10 “(3) update such guidelines as appropriate, in-
11 cluding based on input received pursuant to sub-
12 sections (c) and (f), to address new and emerging
13 public health threats.

14 “(c) CONSIDERATIONS.—In identifying, developing,
15 and updating guidelines under subsection (b), the Assist-
16 ant Secretary for Preparedness and Response shall—

17 “(1) include input from hospitals and health
18 care facilities (including health care coalitions under
19 section 319C–2), State, local, tribal, and territorial
20 public health departments, and health care or sub-
21 ject matter experts (including experts with relevant
22 expertise in chemical, biological, radiological, or nu-
23 clear threats, and emerging infectious disease), as
24 the Assistant Secretary determines appropriate, to
25 meet the goals under section 2802(b)(3);

1 “(2) consult and engage with appropriate
2 health care providers and professionals, including
3 physicians, nurses, first responders, health care fa-
4 cilities (including hospitals, primary care clinics,
5 community health centers, mental health facilities,
6 ambulatory care facilities, and dental health facili-
7 ties), pharmacies, emergency medical providers,
8 trauma care providers, environmental health agen-
9 cies, public health laboratories, poison control cen-
10 ters, blood banks, and other experts that the Assist-
11 ant Secretary determines appropriate, to meet the
12 goals under section 2802(b)(3);

13 “(3) consider feedback related to financial im-
14 plications for hospitals, health care facilities, public
15 health agencies, laboratories, blood banks, and other
16 entities engaged in regional preparedness planning
17 to implement and follow such guidelines, as applica-
18 ble; and

19 “(4) consider financial requirements and poten-
20 tial incentives for entities to prepare for, and re-
21 spond to, public health emergencies as part of the
22 regional health care emergency preparedness and re-
23 sponse system.

24 “(d) TECHNICAL ASSISTANCE.—The Assistant Sec-
25 retary for Preparedness and Response, in consultation

1 with the Director of the Centers for Disease Control and
2 Prevention and the Assistant Secretary of Labor for Occu-
3 pational Safety and Health, may provide technical assist-
4 ance and consultation towards meeting the guidelines de-
5 scribed in subsection (b).

6 “(e) DEMONSTRATION PROJECT FOR REGIONAL
7 HEALTH CARE PREPAREDNESS AND RESPONSE SYS-
8 TEMS.—

9 “(1) IN GENERAL.—The Assistant Secretary for
10 Preparedness and Response may establish a dem-
11 onstration project pursuant to the development and
12 implementation of guidelines under subsection (b) to
13 award grants to improve medical surge capacity for
14 all hazards, build and integrate regional medical re-
15 sponse capabilities, improve specialty care expertise
16 for all-hazards response, and coordinate medical pre-
17 paredness and response across State, local, tribal,
18 territorial, and regional jurisdictions.

19 “(2) SUNSET.—The authority under this sub-
20 section shall expire on September 30, 2023.

21 “(f) GAO REPORT TO CONGRESS.—

22 “(1) REPORT.—Not later than 3 years after the
23 date of enactment of this section, the Comptroller
24 General of the United States (referred to in this
25 subsection as the ‘Comptroller General’) shall submit

1 to the Committee on Health, Education, Labor, and
2 Pensions and the Committee on Finance of the Sen-
3 ate and the Committee on Energy and Commerce
4 and the Committee on Ways and Means of the
5 House of Representatives a report on the extent to
6 which hospitals and health care facilities have imple-
7 mented the recommended guidelines under sub-
8 section (b), including an analysis and evaluation of
9 any challenges hospitals or health care facilities ex-
10 perience in implementing such guidelines.

11 “(2) CONTENT.—The Comptroller General shall
12 include in the report under paragraph (1)—

13 “(A) data on the preparedness and re-
14 sponse capabilities that have been informed by
15 the guidelines under subsection (b) to improve
16 regional emergency health care preparedness
17 and response capability, including hospital and
18 health care facility capacity and medical surge
19 capabilities to prepare for, and respond to, pub-
20 lic health emergencies; and

21 “(B) recommendations to reduce gaps in
22 incentives for regional health partners, includ-
23 ing hospitals and health care facilities, to im-
24 prove capacity and medical surge capabilities to
25 prepare for, and respond to, public health emer-

1 agencies, consistent with subsection (a), which
2 may include consideration of facilities partici-
3 pating in programs under section 319C–2, pro-
4 grams under the Centers for Medicare & Med-
5 icaid Services (including innovative health care
6 delivery and payment models), and input from
7 private sector financial institutions.

8 “(3) CONSULTATION.—In carrying out para-
9 graphs (1) and (2), the Comptroller General shall
10 consult with the heads of appropriate Federal agen-
11 cies, including—

12 “(A) the Assistant Secretary for Prepared-
13 ness and Response;

14 “(B) the Director of the Centers for Dis-
15 ease Control and Prevention;

16 “(C) the Administrator of the Centers for
17 Medicare & Medicaid Services;

18 “(D) the Assistant Secretary for Mental
19 Health and Substance Use;

20 “(E) the Assistant Secretary of Labor for
21 Occupational Safety and Health; and

22 “(F) the Secretary of Veterans Affairs.”.

1 **SEC. 208. NATIONAL ACADEMY OF MEDICINE EVALUATION**
2 **AND REPORT ON THE PREPAREDNESS OF**
3 **HOSPITALS, LONG-TERM CARE FACILITIES,**
4 **DIALYSIS CENTERS, AND OTHER MEDICAL**
5 **FACILITIES FOR PUBLIC HEALTH EMER-**
6 **GENCIES.**

7 (a) EVALUATION.—

8 (1) IN GENERAL.—As soon as possible, but not
9 later than 6 months after the date of enactment of
10 this Act, the Secretary of Health and Human Serv-
11 ices shall enter into an arrangement with the Na-
12 tional Academy of Medicine or, if the National Acad-
13 emy declines to enter into such an arrangement, an-
14 other appropriate entity under which the National
15 Academy (or other appropriate entity) agrees to
16 evaluate the preparedness of hospitals, long-term
17 care facilities, dialysis centers, and other medical fa-
18 cilities nationwide for public health emergencies, in-
19 cluding natural disasters.

20 (2) ARRAY OF EXPERTS.—The arrangement
21 under paragraph (1) shall require the National
22 Academy (or other appropriate entity) to engage an
23 array of experts, including appropriate government
24 experts, when conducting the evaluation under para-
25 graph (1).

1 (3) SPECIFIC MATTERS EVALUATED.—The ar-
2 rangement under paragraph (1) shall require the
3 National Academy of Medicine (or other appropriate
4 entity)—

5 (A) to catalogue, review, and evaluate the
6 efficacy of current rules and regulations for
7 hospitals, long-term care facilities, dialysis cen-
8 ters, and medical facilities regarding emergency
9 preparedness planning;

10 (B) to identify and prioritize options to im-
11 plement policies for hospitals, long-term care
12 facilities, dialysis centers, and other medical fa-
13 cilities nationwide that address future threats;

14 (C) to review all Federal grant programs
15 that affect the preparedness of hospitals, long-
16 term care facilities, dialysis centers, or other
17 medical facilities for public health emergencies
18 and provide recommendations for improving
19 such preparedness by—

20 (i) improving such existing Federal
21 grant programs; or

22 (ii) creating new Federal grant pro-
23 grams;

24 (D) to review, identify, and recommend
25 best practices for improving emergency pre-

1 paredness at hospitals, long-term care facilities,
2 dialysis centers, and other medical facilities;

3 (E) to identify and recommend best
4 sources and guidelines for alternative or emer-
5 gency power systems, including renewable
6 sources, battery storage, and generators; and

7 (F) to identify and recommend best prac-
8 tices and guidelines for emergency preparedness
9 planning related to access to clean water at hos-
10 pitals, long-term care facilities, dialysis centers,
11 and other medical facilities.

12 (b) REPORT.—

13 (1) IN GENERAL.—The arrangement under sub-
14 section (a)(1) shall require the National Academy of
15 Medicine (or other appropriate entity) to submit to
16 the Secretary of Health and Human Services and
17 the Congress, not later than 3 years after the date
18 of enactment of this Act, a report on the results of
19 the evaluation conducted pursuant to this section.

20 (2) CONTENTS.—The report under paragraph
21 (1) shall—

22 (A) describe the findings and conclusions
23 of the evaluation conducted pursuant to this
24 section; and

1 (B) include a strategy for improving the
2 preparedness of hospitals, long-term care facili-
3 ties, dialysis centers, and other medical facili-
4 ties nationwide for public health emergencies,
5 including natural disasters.

6 **SEC. 209. LIMITATION ON LIABILITY FOR VOLUNTEER**
7 **HEALTH CARE PROFESSIONALS.**

8 (a) IN GENERAL.—Title II of the Public Health Serv-
9 ice Act is amended by inserting after section 224 (42
10 U.S.C. 233) the following new section:

11 **“SEC. 224A. LIMITATION ON LIABILITY FOR VOLUNTEER**
12 **HEALTH CARE PROFESSIONALS.**

13 “(a) LIMITATION ON LIABILITY.—Except as provided
14 in subsection (b), a health care professional serving, for
15 purposes of responding to a disaster, as a volunteer shall
16 not be liable under Federal or State law for any harm
17 caused by an act or omission of the professional in the
18 provision of health care services if the act or omission oc-
19 curs—

20 “(1) during the period of the disaster;

21 “(2) in the State or States for which the dis-
22 aster is declared;

23 “(3) while the health care professional is acting
24 in the professional’s capacity as a volunteer;

1 “(4) in the course of providing health care serv-
2 ices that are within the scope of the license, registra-
3 tion, or certification of the volunteer, as defined by
4 the State of licensure, registration, or certification;
5 and

6 “(5) while the health care professional is acting
7 in a good faith belief that the individual being pro-
8 vided such health care services is in need of such
9 health care services.

10 “(b) EXCEPTIONS.—Subsection (a) does not apply
11 with respect to harm caused by an act or omission of a
12 health care professional in the provision of health care
13 services as described in such subsection if—

14 “(1) the harm was caused by an act or omission
15 constituting willful or criminal misconduct, gross
16 negligence, reckless misconduct, or a conscious fla-
17 grant indifference to the rights or safety of the indi-
18 vidual harmed by the health care professional; or

19 “(2) the health care professional provided such
20 health care services under the influence (as deter-
21 mined pursuant to applicable State law) of alcohol
22 or an intoxicating drug.

23 “(c) PREEMPTION.—No State or political subdivision
24 of a State may establish or continue in effect any laws
25 relating to the liability for acts or omissions relating to

1 the provision of health care services by health care profes-
2 sionals serving, for purposes of responding to a disaster,
3 as volunteers that are inconsistent with this section, unless
4 such laws provide greater protection from such liability.

5 “(d) RELATIONSHIP TO VOLUNTEER PROTECTION
6 ACT OF 1997.—The protections from liability under this
7 section are in addition to the protections from liability
8 under the Volunteer Protection Act of 1997.

9 “(e) DEFINITIONS.—In this section:

10 “(1) The term ‘disaster’ means—

11 “(A) a national emergency declared by the
12 President under the National Emergencies Act;

13 “(B) an emergency or major disaster de-
14 clared by the President under the Robert T.
15 Stafford Disaster Relief and Emergency Assist-
16 ance Act; or

17 “(C) a public health emergency that is de-
18 termined by the Secretary under section 319 of
19 this Act with respect to one or more States
20 specified in such determination—

21 “(i) during only the initial period cov-
22 ered by such determination; and

23 “(ii) excluding any period covered by
24 a renewal of such determination.

1 “(2) The term ‘harm’ includes physical, non-
2 physical, economic, and noneconomic losses.

3 “(3) The term ‘health care professional’ means
4 an individual who is licensed, registered, or certified
5 under Federal or State law to provide health care
6 services.

7 “(4) The term ‘health care services’ means any
8 services provided by a health care professional, or by
9 any individual working under the supervision of a
10 health care professional, that relate to—

11 “(A) the diagnosis, prevention, or treat-
12 ment of any human disease or impairment; or

13 “(B) the assessment or care of the health
14 of a human being.

15 “(5) The term ‘State’ includes each of the sev-
16 eral States, the District of Columbia, the Common-
17 wealth of Puerto Rico, the United States Virgin Is-
18 lands, Guam, American Samoa, the Northern Mar-
19 iana Islands, and any other territory or possession
20 of the United States.

21 “(6)(A) The term ‘volunteer’ means a health
22 care professional who, in providing health care serv-
23 ices in response to a disaster, does not receive—

24 “(i) compensation; or

1 “(ii) any other thing of value in lieu of
2 compensation, in excess of \$500 per year.

3 “(B) For purposes of subparagraph (A), the
4 term ‘compensation’—

5 “(i) includes payment under any insurance
6 policy or health plan, or under any Federal
7 health care program (as defined in section
8 1128B(f) of the Social Security Act) or State
9 health benefits program; and

10 “(ii) excludes—

11 “(I) reasonable reimbursement or al-
12 lowance for expenses actually incurred;

13 “(II) receipt of paid leave; and

14 “(III) receipt of items to be used ex-
15 clusively for providing the health care serv-
16 ices referred to in subparagraph (A).”.

17 (b) EFFECTIVE DATE.—The amendment made by
18 subsection (a) shall apply with respect to claims for relief
19 for which the act or omission giving rise to the claim oc-
20 curred on or after the date that is 90 days after the date
21 of the enactment of this Act.

22 (c) SENSE OF CONGRESS.—It is the sense of the Con-
23 gress that—

24 (1) health care professionals should be encour-
25 aged to register with the Emergency System for Ad-

1 vance Registration of Volunteer Health Professionals
2 (ESARVHP), and States should employ online reg-
3 istration with the promptest processing possible of
4 such registrations to foster the rapid deployment
5 and utilization of volunteer health care professionals
6 following a disaster;

7 (2) Federal and State agencies and licensing
8 boards should cooperate to facilitate the timely
9 movement of properly licensed volunteer health care
10 professionals to areas affected by a disaster; and

11 (3) the appropriate licensing entities should
12 verify the licenses of volunteer health care profes-
13 sionals serving disaster victims as soon as is reason-
14 ably practical following a disaster.

15 **TITLE III—ACCELERATING MED-**
16 **ICAL COUNTERMEASURE AD-**
17 **VANCED RESEARCH AND DE-**
18 **VELOPMENT**

19 **SEC. 301. STRATEGIC NATIONAL STOCKPILE AND SECURITY**
20 **COUNTERMEASURE PROCUREMENT.**

21 (a) COORDINATION WITH THE ASPR.—Subsection
22 (a)(1) of section 319F–2 of the Public Health Service Act
23 (42 U.S.C. 247d–6b) is amended by inserting “the Assist-
24 ant Secretary for Preparedness and Response and” before

1 “the Director of the Centers for Disease Control and Pre-
2 vention”.

3 (b) EVALUATION OF OBSTACLES TO RAPID DELIV-
4 ERY OF MEDICAL COUNTERMEASURES.—Section 319F–
5 2(a) of the Public Health Service Act (42 U.S.C. 247d–
6 6b(a)) is amended by adding at the end the following:

7 “(4) RAPID DELIVERY STUDY.—The Assistant
8 Secretary for Preparedness and Response may con-
9 duct a study on issues that have the potential to ad-
10 versely affect the handling and rapid delivery of
11 safe, secure, or sterile medical countermeasures to
12 individuals who are at risk during public health
13 emergencies occurring in the United States.

14 “(5) NOTICE TO CONGRESS.—Not later than 9
15 months after the date of the enactment of this para-
16 graph, the Assistant Secretary for Preparedness and
17 Response shall notify the Committee on Energy and
18 Commerce of the House of Representatives and the
19 Committee on Health, Education, Labor, and Pen-
20 sions of the Senate, whether or not the study au-
21 thorized under paragraph (4) will be conducted.

22 “(6) REPORT TO CONGRESS.—If the Assistant
23 Secretary for Preparedness and Response conducts
24 the study authorized under paragraph (4), the As-
25 sistant Secretary, not later than 18 months after the

1 date on which such study is completed, shall submit
2 a report to the Committee on Energy and Commerce
3 of the House of Representatives and the Committee
4 on Health, Education, Labor, and Pensions of the
5 Senate containing the findings of such study.”.

6 (c) CONGRESSIONAL NOTIFICATION OF MATERIAL
7 THREAT DETERMINATION.—Section 319F–2(c)(2)(C) of
8 the Public Health Service Act (42 U.S.C. 247d–
9 6b(c)(2)(C)) is amended by striking “The Secretary and
10 the Homeland Security Secretary shall promptly notify the
11 appropriate committees of Congress” and inserting “The
12 Secretary and the Secretary of Homeland Security shall
13 send to Congress, on an annual basis, all current material
14 threat determinations and shall promptly notify the Com-
15 mittee on Health, Education, Labor, and Pensions and the
16 Committee on Homeland Security and Governmental Af-
17 fairs of the Senate and the Committee on Energy and
18 Commerce and the Committee on Homeland Security of
19 the House of Representatives that a determination has
20 been made pursuant to subparagraph (A) or (B)”.

21 (d) AUTHORIZATION OF APPROPRIATIONS.—Section
22 319F–2(f)(1) of the Public Health Service Act (42 U.S.C.
23 247d–6b(f)(1)) is amended by striking “\$533,800,000 for
24 each of fiscal years 2014 through 2018” and inserting

1 “\$610,000,000 for each of fiscal years 2019 through
2 2023, to remain available until expended”.

3 (e) BIOSHIELD SPECIAL RESERVE FUND.—Para-
4 graph (1) of section 319F–2(g) of the Public Health Serv-
5 ice Act (42 U.S.C. 247d–6b(g)) is amended to read as fol-
6 lows:

7 “(1) AUTHORIZATION OF APPROPRIATIONS.—In
8 addition to amounts appropriated to the special re-
9 serve fund prior to the date of the enactment of this
10 subsection, there is authorized to be appropriated,
11 for the procurement of security countermeasures
12 under subsection (c) and for carrying out section
13 319L (relating to the Biomedical Advanced Research
14 and Development Authority), \$7,100,000,000 for the
15 fiscal years 2019 through 2028. Funds authorized
16 by the preceding sentence for fiscal years 2020
17 through 2027 may be provided by advance appro-
18 priation, to be obligated at a rate of not less than
19 \$710,000,000 per year. Amounts appropriated pur-
20 suant to this paragraph are authorized to remain
21 available until expended.”.

22 **SEC. 302. BIOMEDICAL ADVANCED RESEARCH AND DEVEL-**
23 **OPMENT AUTHORITY.**

24 (a) UPDATING DEFINITION OF OTHER TRANS-
25 ACTIONS.—Section 319L(a)(3) of the Public Health Serv-

1 ice Act (42 U.S.C. 247d–7e(a)(3)) is amended by striking
2 “, such as the Secretary of Defense may enter into under
3 section 2371 of title 10, United States Code”.

4 (b) PREPARING FOR PANDEMIC INFLUENZA, ANTI-
5 MICROBIAL RESISTANCE, AND OTHER SIGNIFICANT
6 THREATS.—Section 319L(c)(4) of the Public Health Serv-
7 ice Act (42 U.S.C. 247d–7e(c)(4)) is amended by adding
8 at the end the following:

9 “(F) STRATEGIC INITIATIVES.—The Sec-
10 retary, acting through the Director of BARDA,
11 may implement strategic initiatives, including
12 by building on existing programs and by award-
13 ing grants supporting innovative candidate
14 products in preclinical and clinical development,
15 to address priority, naturally occurring and
16 man-made threats that, as determined by the
17 Secretary, pose a significant level of risk to na-
18 tional security based on the characteristics of a
19 chemical, biological, radiological, or nuclear
20 threat, or existing capabilities to respond to
21 such a threat (including medical response and
22 treatment capabilities and manufacturing infra-
23 structure). Such initiatives shall accelerate and
24 support the advanced research, development,

1 and procurement of, countermeasures and prod-
2 ucts, as applicable, to address areas including—

3 “(i) chemical, biological, radiological,
4 or nuclear threats, including emerging in-
5 fectionous diseases, for which insufficient ap-
6 proved, licensed, or authorized counter-
7 measures exist, or for which such threat,
8 or the result of an exposure to such threat,
9 may become resistant to countermeasures
10 or existing countermeasures may be ren-
11 dered ineffective;

12 “(ii) threats that consistently exist or
13 continually circulate and have significant
14 potential to become a pandemic, such as
15 pandemic influenza, which may include the
16 advanced research and development, manu-
17 facturing, and appropriate stockpiling of
18 qualified pandemic or epidemic products,
19 and products, technologies, or processes to
20 support the advanced research and devel-
21 opment of such countermeasures (including
22 multiuse platform technologies for
23 diagnostics, vaccines, and therapeutics;
24 virus seeds; clinical trial lots; novel virus

1 strains; and antigen and adjuvant mate-
2 rial); and

3 “(iii) threats that may result pri-
4 marily or secondarily from a chemical, bio-
5 logical, radiological, or nuclear agent, or
6 emerging infectious disease, and which
7 may present increased treatment complica-
8 tions such as the occurrence of resistance
9 to available countermeasures or potential
10 countermeasures, including antimicrobial
11 resistant pathogens.”.

12 (c) TRANSACTION AUTHORITIES.—Section
13 319L(c)(5)(A) of the Public Health Service Act (42
14 U.S.C. 247d–7e(c)(5)(A)) is amended—

15 (1) by amending clause (i) to read as follows:

16 “(i) IN GENERAL.—The Secretary
17 shall have the authority to engage in trans-
18 actions other than a contract, grant, or co-
19 operative agreement with respect to
20 projects under this section.”;

21 (2) in clause (ii)—

22 (A) by amending subclause (I) to read as
23 follows:

24 “(I) To the maximum extent
25 practicable, competitive procedures

1 shall be used when entering into
2 agreements to carry out projects
3 under this section.”; and

4 (B) in subclause (II), by striking
5 “\$20,000,000” and inserting “\$100,000,000”.

6 (d) PANDEMIC INFLUENZA PROGRAM.—Section
7 319L of the Public Health Service Act (42 U.S.C. 247d–
8 7e) is amended—

9 (1) by redesignating subsections (d) through (f)
10 as subsections (f) through (h), respectively; and

11 (2) by inserting after subsection (c) the fol-
12 lowing new subsections:

13 “(d) PANDEMIC INFLUENZA PROGRAM.—The Sec-
14 retary, acting through the Director of BARDA, shall es-
15 tablish and implement a program that—

16 “(1) supports advanced research and develop-
17 ment activities for qualified pandemic or epidemic
18 products (as defined in section 319F–3(i)), including
19 by developing innovative technologies to enhance
20 rapid response to threats relating to pandemic influ-
21 enza;

22 “(2) ensures readiness to respond to pandemic
23 influenza threats by supporting the development and
24 manufacturing of influenza virus seeds, clinical trial
25 lots, and stockpiles of novel influenza strains; and

1 “(3) sustains and replenishes pandemic stock-
2 piles of bulk antigen and adjuvant material, includ-
3 ing annually testing the potency and shelf-life poten-
4 tial of all existing pandemic stockpiles held by the
5 Department of Health and Human Services.

6 “(e) EMERGING INFECTIOUS DISEASE PROGRAM.—
7 The Secretary, acting through the Director of BARDA,
8 shall establish and implement a program that supports ad-
9 vanced research and development activities for qualified
10 pandemic or epidemic products, and manufacturing infra-
11 structure, activities with respect to an emerging infectious
12 disease.”.

13 (e) FUNDING.—Subsection (f) of section 319L of the
14 Public Health Service Act (42 U.S.C. 247d–7e), as redes-
15 ignated by subsection (b)(1), is amended—

16 (1) in paragraph (2)—

17 (A) by inserting “(other than subsections
18 (d) and (e))” after “purposes of this section”;
19 and

20 (B) by striking “\$415,000,000 for each of
21 fiscal years 2014 through 2018” and inserting
22 “\$536,700,000 for each of fiscal years 2019
23 through 2023”; and

24 (2) by adding at the end the following new
25 paragraphs:

1 “(3) FUNDING FOR PANDEMIC INFLUENZA PRO-
2 GRAM.—

3 “(A) IN GENERAL.—To carry out the pur-
4 poses of subsection (d), there is authorized to
5 be appropriated \$250,000,000 for each of fiscal
6 years 2019 through 2023, to remain available
7 until expended.

8 “(B) SUPPLEMENT NOT SUPPLANT.—Any
9 funds provided to the Secretary under this
10 paragraph shall be used to supplement and not
11 supplant any other Federal funds provided to
12 carry out the purposes of subsection (d).

13 “(4) FUNDING FOR EMERGING INFECTIOUS DIS-
14 EASE PROGRAM.—

15 “(A) IN GENERAL.—To carry out the pur-
16 poses of subsection (e), there is authorized to
17 be appropriated \$250,000,000 for each of fiscal
18 years 2019 through 2023, to remain available
19 until expended.

20 “(B) SUPPLEMENT NOT SUPPLANT.—Any
21 funds provided to the Secretary under this
22 paragraph shall be used to supplement and not
23 supplant any other Federal funds provided to
24 carry out the purposes of subsection (e).”.

1 **SEC. 303. REPORT ON THE DEVELOPMENT OF VACCINES TO**
2 **PREVENT FUTURE EPIDEMICS.**

3 Not later than one year after the date of the enact-
4 ment of this Act, the Secretary of Health and Human
5 Services shall submit to Congress a report detailing the
6 activities carried out by the Department of Health and
7 Human Services to support the development of vaccines
8 to prevent future epidemics, including work carried out
9 through domestic and global public-private partnerships
10 and other collaborations intended to spur the development
11 of such vaccines. Such report shall include information re-
12 lated to the provision of any funding or technical assist-
13 ance to such entities.

14 **TITLE IV—MISCELLANEOUS**
15 **PROVISIONS**

16 **SEC. 401. CYBERSECURITY.**

17 (a) NATIONAL HEALTH SECURITY STRATEGY.—Sec-
18 tion 2802(a) of the Public Health Service Act (42 U.S.C.
19 300hh–1(a)) is amended by adding at the end the fol-
20 lowing:

21 “(4) CYBERSECURITY THREATS.—In the next
22 version of the National Health Security Strategy
23 prepared after the date of the enactment of this
24 paragraph, the National Health Security Strategy
25 shall include a national strategy focused on address-

1 ing cybersecurity threats to the public health and
2 health care system, including—

3 “(A) defining the functions, capabilities,
4 and gaps in such system; and

5 “(B) identifying strategies to strengthen
6 the preparedness and response of such system
7 to cybersecurity threats and incidents, including
8 with respect to continuity of care and risk miti-
9 gation to prevent harm to human health in case
10 of a cybersecurity incident.”.

11 (b) COORDINATION OF PREPAREDNESS FOR AND RE-
12 SPONSE TO ALL-HAZARDS PUBLIC HEALTH EMER-
13 GENCIES.—Section 2811(c) of the Public Health Service
14 Act (42 U.S.C. 300hh–10), as amended by sections 101
15 and 301, is further amended—

16 (1) by redesignating paragraph (4) as para-
17 graph (5); and

18 (2) by inserting after paragraph (3) the fol-
19 lowing:

20 “(4) have lead responsibility within the Depart-
21 ment of Health and Human Services for coordi-
22 nating preparedness, response, and recovery activi-
23 ties within the health care sector to provide con-
24 tinuity of care during a cybersecurity incident; and”.

1 **SEC. 402. MISCELLANEOUS FDA AMENDMENTS.**

2 (a) DRUG DEVELOPMENT TOOLS.—Section 507(c) of
3 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
4 357) is amended—

5 (1) by redesignating paragraph (3) as para-
6 graph (4); and

7 (2) by inserting after paragraph (2) the fol-
8 lowing:

9 “(3) NATIONAL SECURITY LIMITATION.—In
10 making information publicly available pursuant to
11 paragraph (1), the Secretary—

12 “(A) shall not disclose information that
13 would compromise national security; and

14 “(B) may make available summaries in
15 lieu of data and evidence contained in qualifica-
16 tion submissions.”.

17 (b) EMERGENCY USE INSTRUCTIONS.—Subpara-
18 graph (A) of section 564A(e)(2) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a(e)(2)) is
20 amended by striking “subsection (a)(1)(C)(i)” and insert-
21 ing “subsection (a)(1)(C)”.

22 (c) PRODUCTS HELD FOR EMERGENCY USE.—Sec-
23 tion 564B(2) of the Federal Food, Drug, and Cosmetic
24 Act (21 U.S.C. 360bbb–3b) is amended—

25 (1) in subparagraph (B), by inserting a comma
26 after “505”; and

1 (2) in subparagraph (C), by inserting “or sec-
2 tion 564A” before the period at the end.

3 (d) REGULATORY MANAGEMENT PLANS.—Section
4 565(f) of the Federal Food, Drug and Cosmetic Act (21
5 U.S.C. 360bbb–4(f)) is amended—

6 (1) by redesignating paragraphs (3) through
7 (6) as paragraphs (4) through (7), respectively;

8 (2) by inserting after paragraph (2) the fol-
9 lowing:

10 “(3) PUBLICATION.—The Secretary shall make
11 available on the internet website of the Food and
12 Drug Administration information regarding regu-
13 latory management plans, including—

14 “(A) the process by which an applicant
15 may submit a request for a regulatory manage-
16 ment plan;

17 “(B) the timeframe by which the Secretary
18 is required to respond to such request;

19 “(C) the information required for the sub-
20 mission of such request;

21 “(D) a description of the types of develop-
22 ment milestones and performance targets that
23 could be discussed and included in such plans;
24 and

1 “(E) contact information for beginning the
2 regulatory management plan process.”;

3 (3) in paragraph (6), as so redesignated, in the
4 matter preceding subparagraph (A)—

5 (A) by striking “paragraph (4)(A)” and in-
6 serting “paragraph (5)(A)”; and

7 (B) by striking “paragraph (4)(B)” and
8 inserting “paragraph (5)(B)”; and

9 (4) in paragraph (7)(A), as so redesignated, by
10 striking “paragraph (3)(A)” and inserting “para-
11 graph (4)(A)”.

12 (e) ANIMAL RULE REPORT.—

13 (1) STUDY.—The Comptroller General of the
14 United States shall conduct a study on the applica-
15 tion of the requirements under section 565(d) of the
16 of the Federal Food, Drug, and Cosmetic Act (21
17 U.S.C. 360bbb–4(d)) (referred to in this section as
18 the “animal rule”) as a component of medical coun-
19 termeasure advanced development under the Bio-
20 medical Advanced Research and Development Au-
21 thority and regulatory review by the Food and Drug
22 Administration. In conducting such study, the
23 Comptroller General shall examine the following:

24 (A) The extent to which advanced develop-
25 ment and review of a medical countermeasure

1 are coordinated between the Biomedical Ad-
2 vanced Research and Development Authority
3 and the Food and Drug Administration, includ-
4 ing activities to facilitate appropriate and effi-
5 cient design of studies to support approval, li-
6 censure, and authorization under the animal
7 rule, consistent with the recommendations in
8 the animal rule guidance, issued pursuant to
9 section 565(c) of the Federal Food Drug and
10 Cosmetic Act (21 U.S.C. 360bbb–4(c)) and en-
11 titled “Product Development Under the Animal
12 Rule Guidance for Industry” (issued in October
13 2015), to resolve discrepancies in the design of
14 adequate and well-controlled efficacy studies
15 conducted in animal models related to the pro-
16 vision of substantial evidence of effectiveness
17 for the product approved, licensed, or author-
18 ized under the animal rule.

19 (B) The consistency of the application of
20 the animal rule among and between review divi-
21 sions within the Food and Drug Administra-
22 tion.

23 (C) The flexibilities pursuant to the animal
24 rule to address variations in countermeasure de-
25 velopment and review processes, including the

1 extent to which qualified animal models are
2 adopted and used within the Food and Drug
3 Administration in regulatory decisionmaking
4 with respect to medical countermeasures.

5 (D) The extent to which the guidance
6 issued under section 565(c) of the Federal Food
7 Drug and Cosmetic Act (21 U.S.C. 360bbb–
8 4(c)), entitled, “Product Development Under
9 the Animal Rule Guidance for Industry” (issued
10 in October 2015), has assisted in achieving the
11 purposes described in subparagraphs (A), (B),
12 and (C).

13 (2) CONSULTATIONS.—In conducting the study
14 under paragraph (1), the Comptroller General of the
15 United States shall consult with—

16 (A) the Federal agencies responsible for
17 advancing, reviewing, and procuring medical
18 countermeasures, including the Office of the
19 Assistant Secretary for Preparedness and Re-
20 sponse, the Biomedical Advanced Research and
21 Development Authority, the Food and Drug Ad-
22 ministration, and the Department of Defense;

23 (B) manufacturers involved in the research
24 and development of medical countermeasures to

1 address biological, chemical, radiological, and
2 nuclear threats; and

3 (C) other biodefense stakeholders, as appli-
4 cable.

5 (3) REPORT.—Not later than 3 years after the
6 date of enactment of this Act, the Comptroller Gen-
7 eral of the United States shall submit to the Com-
8 mittee on Health, Education, Labor, and Pensions
9 of the Senate and the Committee on Energy and
10 Commerce of the House of Representatives a report
11 containing the results of the study conducted under
12 paragraph (1) and recommendations to improve the
13 application and consistency of the requirements
14 under subsections (c) and (d) of section 565 of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 360bbb–4) to support and expedite the research and
17 development of medical countermeasures, as applica-
18 ble.

19 (4) PROTECTION OF NATIONAL SECURITY.—
20 The Comptroller General of the United States shall
21 conduct the study and issue the assessment and re-
22 port under this subsection in a manner that does not
23 compromise national security.

1 **SEC. 403. MEDICAL COUNTERMEASURE MASTER FILES.**

2 (a) IN GENERAL.—Chapter V of the Federal Food,
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-
4 ed by inserting after section 565A the following:

5 **“SEC. 565B. MEDICAL COUNTERMEASURE MASTER FILES.**

6 “(a) APPLICABILITY OF REFERENCE.—

7 “(1) IN GENERAL.—A person may submit data
8 and information in a master file to the Secretary
9 with the intent to reference, or to authorize, in writ-
10 ing, another person to reference, such data or infor-
11 mation to support a medical countermeasure submis-
12 sion (including a supplement or amendment to any
13 such submission), without requiring the master file
14 holder to disclose the data and information to any
15 such persons authorized to reference the master file.
16 Such data and information shall be available for ref-
17 erence by the master file holder or a person author-
18 ized by the master file holder only in accordance
19 with applicable privacy and confidentiality protocols
20 and regulations.

21 “(2) LIMITATION.—Notwithstanding paragraph
22 (1), a person may not reference, or authorize an-
23 other person to reference, data or information to
24 support a medical countermeasure submission to the
25 extent such data or information is in the master file

1 for an application for conditional approval under
2 section 571.

3 “(b) MEDICAL COUNTERMEASURE MASTER FILE
4 CONTENT.—

5 “(1) IN GENERAL.—A medical countermeasure
6 master file may include data and information to sup-
7 port—

8 “(A) the development of medical counter-
9 measure submissions to support the approval,
10 licensure, classification, clearance, conditional
11 approval, or authorization of one or more secu-
12 rity countermeasures, qualified counter-
13 measures, or qualified pandemic or epidemic
14 products; and

15 “(B) the manufacture of security counter-
16 measures, qualified countermeasures, or quali-
17 fied pandemic or epidemic products.

18 “(2) REQUIRED UPDATES.—The Secretary may
19 require, as appropriate, that the master file holder
20 ensure that the contents of such master file are up-
21 dated during the time such master file is referenced
22 for a medical countermeasure submission.

23 “(c) SPONSOR REFERENCE.—

24 “(1) IN GENERAL.—Each incorporation of data
25 or information contained in a master file by ref-

1 erence shall describe the incorporated material in a
2 manner in which the Secretary determines appro-
3 priate and that permits the review of such data or
4 information without necessitating resubmission of
5 such data or information. Master files shall be sub-
6 mitted in an electronic format in accordance with
7 section 745A and as specified in applicable guidance.

8 “(2) REFERENCE BY A MASTER FILE HOLD-
9 ER.—A master file holder that is the sponsor of a
10 medical countermeasure submission shall notify the
11 Secretary in writing of the intent to reference the
12 medical countermeasure master file as a part of the
13 submission.

14 “(3) REFERENCE BY AN AUTHORIZED PER-
15 SON.—A sponsor of a medical countermeasure sub-
16 mission may, where the Secretary determines appro-
17 priate, incorporate by reference all or part of the
18 contents of a medical countermeasure master file, if
19 the master file holder authorizes the incorporation in
20 writing.

21 “(d) ACKNOWLEDGMENT OF MASTER FILE BY THE
22 SECRETARY.—The Secretary shall provide the master file
23 holder with a written notification indicating that the Sec-
24 retary has reviewed and relied upon specified data or in-
25 formation within a master file and the purposes for which

1 such data or information was incorporated by reference
2 if the Secretary has reviewed and relied upon such speci-
3 fied data or information to support the approval, classi-
4 fication, conditional approval, clearance, licensure, or au-
5 thorization of a security countermeasure, qualified coun-
6 termeasure, or qualified pandemic or epidemic product.
7 The Secretary may rely upon the data and information
8 within the medical countermeasure master file for which
9 such written notification was provided in additional appli-
10 cations, as applicable and appropriate and upon the re-
11 quest of the master file holder so notified in writing or
12 by an authorized person of such holder.

13 “(e) RULES OF CONSTRUCTION.—Nothing in this
14 section shall be construed to—

15 “(1) alter the authority of the Secretary to ap-
16 prove, license, classify, clear, conditionally approve,
17 or authorize drugs, biological products, or devices
18 pursuant to this Act or section 351 of the Public
19 Health Service Act (as authorized prior to the date
20 of enactment of the Pandemic and All-Hazards Pre-
21 paredness and Advancing Innovation Act of 2018),
22 including the standards of evidence, and applicable
23 conditions, for approval under the applicable Act; or

24 “(2) alter the authority of the Secretary under
25 this Act or the Public Health Service Act to deter-

1 mine the types of data or information previously
2 submitted by a sponsor or any other person that
3 may be incorporated by reference in an application,
4 request, or notification for a drug, biological prod-
5 uct, or device submitted under section 505(i),
6 505(b), 505(j), 512(b)(1), 512(b)(2), 564, 571,
7 520(g), 515(c), 513(f)(2), or 510(k) of this Act, or
8 subsection (a) or (k) of section 351 of the Public
9 Health Service Act, including a supplement or
10 amendment to any such submission, and the require-
11 ments associated with such reference.

12 “(f) DEFINITIONS.—In this section:

13 “(1) The term ‘master file holder’ means a per-
14 son who submits data and information to the Sec-
15 retary with the intent to reference or authorize to
16 reference such data or information to support a
17 medical countermeasure submission, as described in
18 subsection (a)(1).

19 “(2) The term ‘medical countermeasure submis-
20 sion’ means an investigational new drug application
21 under section 505(i), a new drug application under
22 section 505(b), or an abbreviated new drug applica-
23 tion under section 505(j) of this Act, a biological
24 product license application under section 351(a) of
25 the Public Health Service Act or a biosimilar biologi-

1 cal product license application under section 351(k)
2 of the Public Health Service Act, a new animal drug
3 application under section 512(b)(1) or abbreviated
4 new animal drug application under section
5 512(b)(2), an application for conditional approval of
6 a new animal drug under 571, an investigational de-
7 vice application under section 520(g), an application
8 with respect to a device under section 515(c), a re-
9 quest for classification of a device under section
10 513(f)(2), a notification with respect to a device
11 under section 510(k), or request for an emergency
12 use authorization under section 564 to support—

13 “(A) the approval, licensure, classification,
14 clearance, conditional approval, or authorization
15 of a security countermeasure, qualified counter-
16 measure, or qualified pandemic or epidemic
17 product; or

18 “(B) a new indication to an approved secu-
19 rity countermeasure, qualified countermeasure,
20 or qualified pandemic or epidemic product.

21 “(3) The terms ‘qualified countermeasure’, ‘se-
22 curity countermeasure’, and ‘qualified pandemic or
23 epidemic product’ have the meanings given such
24 terms in sections 319F–1, 319F–2, and 319F–3, re-
25 spectively, of the Public Health Service Act.”.

1 (b) STAKEHOLDER INPUT.—Not later than 18
2 months after the date of enactment of this Act, the Sec-
3 retary of Health and Human Services (referred to in this
4 section as the “Secretary”), acting through the Commis-
5 sioner of Food and Drugs and in consultation with the
6 Assistant Secretary for Preparedness and Response, shall
7 solicit input from stakeholders, including stakeholders de-
8 veloping security countermeasures, qualified counter-
9 measures, or qualified pandemic or epidemic products, and
10 stakeholders developing technologies to assist in the devel-
11 opment of such countermeasures with respect to how the
12 Food and Drug Administration can advance the use of
13 tools and technologies to support and accelerate the devel-
14 opment or manufacture of security countermeasures,
15 qualified countermeasures, and qualified pandemic or epi-
16 demic products, including through the reliance on cross-
17 referenced data and information contained within master
18 files and submissions previously submitted to the Sec-
19 retary as set forth in section 565B of the Federal Food,
20 Drug, and Cosmetic Act, as added by subsection (a).

21 (c) GUIDANCE.—Not later than 2 years after the
22 after the date of enactment of this Act, the Secretary, act-
23 ing through the Commissioner of Food and Drugs, shall
24 publish draft guidance about how reliance on cross-ref-
25 erenced data and information contained within master

1 files under section 565B of the Federal Food, Drug, and
2 Cosmetic Act, as added by subsection (a), or submissions
3 otherwise submitted to the Secretary may be used for spe-
4 cific tools or technologies (including platform technologies)
5 that have the potential to support and accelerate the devel-
6 opment or manufacture of security countermeasures,
7 qualified countermeasures, qualified pandemic or epidemic
8 products. The Secretary, acting through the Commissioner
9 of Food and Drugs, shall publish the final guidance not
10 later than 3 years after the enactment of this Act.

11 **SEC. 404. FORMAL STRATEGY RELATING TO CHILDREN**
12 **SEPARATED FROM PARENTS AND GUARD-**
13 **IANAS AS A RESULT OF “ZERO TOLERANCE”**
14 **POLICY.**

15 Not later than 14 days after the date of the enact-
16 ment of this Act, the Assistant Secretary for Preparedness
17 and Response shall submit to the Committee on Energy
18 and Commerce of the House of Representatives a formal
19 strategy—

20 (1) to reunify with their parent or guardian
21 each child who, as a result of the “zero tolerance”
22 policy, was separated from their parent or guardian
23 and placed into a facility funded by the Department
24 of Health and Human Services; and

1 (2) to address deficiencies identified by the pre-
2 vious work of the Committee, which began in 2014,
3 regarding the oversight of, and care for, unaccom-
4 panied alien children in the custody of the Depart-
5 ment.

6 **SEC. 405. BIOLOGICAL THREAT DETECTION.**

7 Part B of title III of the Public Health Service Act
8 (42 U.S.C. 243 et seq.), as amended by section 104, is
9 further amended by inserting after section 319D–1 of
10 such Act, the following new section:

11 **“SEC. 319D–2. BIOLOGICAL THREAT DETECTION.**

12 “(a) EXCHANGE OF INFORMATION.—

13 “(1) IN GENERAL.—The Secretary of Health
14 and Human Services, in coordination with the Sec-
15 retary of Defense and the Secretary of Homeland
16 Security, shall—

17 “(A) facilitate the identification by Federal
18 departments and agencies of technological,
19 operational, and programmatic successes and
20 failures of domestic detection programs for in-
21 tentionally introduced, accidentally released,
22 and naturally occurring infectious diseases;

23 “(B) facilitate the exchange of information
24 described in subparagraph (A) among Federal

1 departments and agencies that utilize biological
2 threat detection technology; and

3 “(C) make recommendations on research,
4 development, and procurement to Federal de-
5 partments and agencies to replace and enhance
6 biological threat detection systems in use, in-
7 cluding recommendation for the transfer of bio-
8 logical threat detection technology among Fed-
9 eral departments and agencies.

10 “(2) CONSIDERATIONS.—In carrying out para-
11 graph (1), the Secretary of Health and Human
12 Services shall take into consideration the capabilities
13 of the system with respect to each of the following:

14 “(A) Rapidly detecting, identifying, charac-
15 terizing, and confirming the presence of biologi-
16 cal threat agents.

17 “(B) Recovering live biological agents from
18 collection devices.

19 “(C) Determining the geographical dis-
20 tribution of biological agents.

21 “(D) Determining the extent of environ-
22 mental contamination and persistence of bio-
23 logical agents.

24 “(E) Providing advanced molecular
25 diagnostics to State, local, tribal, and territorial

1 public health and other laboratories that sup-
2 port biological threat detection activities.

3 “(b) COLLABORATION.—The Secretary of Health and
4 Human Services, in consultation with Secretary of De-
5 fense, the Secretary of Homeland Security, the Director
6 of the Centers for Disease Control and Prevention, and
7 the heads of other Federal departments and agencies that
8 utilize biological threat detection technology, shall collabo-
9 rate with State, local, tribal, and territorial public health
10 laboratories and other users of current and future biologi-
11 cal threat detection systems to develop—

12 “(1) biological threat detection requirements,
13 including—

14 “(A) technical, quality, and biosafety
15 standards, including the review of validation
16 data prior to and throughout deployment of a
17 biological threat detection system; and

18 “(B) requirements for—

19 “(i) the assessment of quality stand-
20 ards and the development and deployment
21 of biological threat detection systems; and

22 “(ii) metrics for, collaborative assess-
23 ment of, and deployment of biosafety
24 standards;

25 “(2) a standardized integration strategy for—

1 “(A) the level to which biological threat de-
2 tection processes and systems are defined and
3 executed;

4 “(B) the locations at which such processes
5 and systems are performed; and

6 “(C) the extent to which data is shared
7 among State, local, tribal, and territorial public
8 health laboratories and Federal departments
9 and agencies;

10 “(3) State, local, tribal, and territorial labora-
11 tory training requirements for—

12 “(A) supporting and participating in bio-
13 logical threat detection systems; and

14 “(B) addressing flexibility at the jurisdic-
15 tional level allowing for adoption of technology
16 based on need and assessment of the efficacy
17 and local utility of technology by the jurisdic-
18 tion;

19 “(4) guidelines for a coordinated public health
20 response addressing all aspects of a response, includ-
21 ing clinical and epidemiological guidelines for uti-
22 lizing information produced by biological threat de-
23 tection systems and responding to intentionally in-
24 troduced, accidentally released, and naturally occur-
25 ring infectious diseases; and

1 “(5) a coordinated remediation plan with Fed-
2 eral departments and agencies and State and local
3 public health agencies to facilitate rapid, safe, and
4 coordinated restoration of facilities and localities
5 after a contaminating biological event.”.

6 **SEC. 406. STRENGTHENING MOSQUITO ABATEMENT FOR**
7 **SAFETY AND HEALTH.**

8 (a) REAUTHORIZATION OF MOSQUITO ABATEMENT
9 FOR SAFETY AND HEALTH PROGRAM.—Section 317S of
10 the Public Health Service Act (42 U.S.C. 247b–21) is
11 amended—

12 (1) in subsection (a)(1)(B)—

13 (A) by inserting “including programs to
14 address emerging infectious mosquito-borne dis-
15 eases,” after “subdivisions for control pro-
16 grams,”; and

17 (B) by inserting “or improving existing
18 control programs” before the period at the end;

19 (2) in subsection (b)—

20 (A) in paragraph (1), by inserting “, in-
21 cluding improvement,” after “operation”;

22 (B) in paragraph (2)—

23 (i) in subparagraph (A)—

24 (I) in clause (ii), by striking “or”
25 at the end;

1 (II) in clause (iii), by striking the
2 semicolon at the end and inserting “,
3 including an emerging infectious mos-
4 quito-borne disease that presents a se-
5 rious public health threat; or”; and

6 (III) by adding at the end the
7 following:

8 “(iv) a public health emergency due to
9 the incidence or prevalence of a mosquito-
10 borne disease that presents a serious pub-
11 lic health threat;”; and

12 (ii) by amending subparagraph (D) to
13 read as follows:

14 “(D)(i) is located in a State that has re-
15 ceived a grant under subsection (a); or

16 “(ii) demonstrates to the Secretary that
17 the control program for which a grant is sought
18 is consistent with existing State mosquito con-
19 trol plans or policies, and other applicable State
20 preparedness plans.”;

21 (C) in paragraph (4)(C), by striking “that
22 extraordinary” and all that follows through the
23 period at the end and inserting the following:
24 “that—

1 “(i) extraordinary economic conditions
2 in the political subdivision or consortium of
3 political subdivisions involved justify the
4 waiver; or

5 “(ii) the geographical area covered by
6 a political subdivision or consortium for a
7 grant under paragraph (1) has an extreme
8 mosquito control need due to—

9 “(I) the size or density of the po-
10 tentially impacted human population;

11 “(II) the size or density of a
12 mosquito population that requires
13 heightened control; or

14 “(III) the severity of the mos-
15 quito-borne disease, such that ex-
16 pected serious adverse health out-
17 comes for the human population jus-
18 tify the waiver.”; and

19 (D) by amending paragraph (6) to read as
20 follows:

21 “(6) NUMBER OF GRANTS.—A political subdivi-
22 sion or a consortium of political subdivisions may
23 not receive more than one grant under paragraph
24 (1).”; and

1 (3) in subsection (d), by striking “Amounts ap-
2 propriated under subsection (f)” and inserting
3 “Amounts appropriated to carry out this section”.

4 (b) EPIDEMIOLOGY-LABORATORY CAPACITY
5 GRANTS.—Section 2821 of the Public Health Service Act
6 (42 U.S.C. 300hh–31) is amended—

7 (1) in subsection (a)(1), by inserting “, includ-
8 ing mosquito and other vector-borne diseases,” after
9 “infectious diseases”; and

10 (2) by amending subsection (b) to read as fol-
11 lows:

12 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this section
14 \$40,000,000 for each of fiscal years 2019 through 2023.”.

15 (c) GAO STUDY.—

16 (1) STUDY.—The Comptroller General of the
17 United States shall conduct a study on the state of
18 surveillance and control of mosquito-borne infectious
19 diseases in the United States, including Indian coun-
20 try (as defined in section 1151 of title 18, United
21 States Code) and territories, including the state of
22 preparedness for conducting such surveillance and
23 control. The study shall include—

24 (A) a description of the infrastructure and
25 programs for mosquito control in the United

1 States (including Indian country (as so defined)
2 and such territories), including—

3 (i) how such infrastructure and pro-
4 grams are organized and implemented at
5 the Federal, State and local levels, includ-
6 ing with respect to departments and agen-
7 cies of the States, and local organizations
8 (including special districts) involved in
9 such control programs;

10 (ii) the role of the private sector in
11 such activities;

12 (iii) how the authority for mosquito
13 control impacts such activities; and

14 (iv) the funding sources for such in-
15 frastructure and programs, including Fed-
16 eral, State, and local funding sources;

17 (B) how mosquito-borne and other vector-
18 borne disease surveillance and control is inte-
19 grated into Federal, State, and local prepared-
20 ness plans and actions, including how zoonotic
21 surveillance is integrated into infectious disease
22 surveillance to support real-time situational sur-
23 veillance and awareness;

24 (C) Federal, State, and local laboratory ca-
25 pacity for emerging vector-borne diseases, in-

1 including mosquito-borne and other zoonotic dis-
2 eases; and

3 (D) any regulatory challenges for devel-
4 oping and utilizing vector-control technologies
5 and platforms as part of mosquito control strat-
6 egies.

7 (2) CONSULTATIONS.—In conducting the study
8 under paragraph (1), the Comptroller General of the
9 United States shall consult with—

10 (A) State and local public health officials
11 involved in mosquito and other vector-borne dis-
12 ease surveillance and control efforts;

13 (B) researchers and manufacturers of mos-
14 quito control products;

15 (C) stakeholders involved in mosquito
16 abatement activities;

17 (D) infectious disease experts; and

18 (E) entomologists involved in mosquito-
19 borne disease surveillance and control efforts.

20 (3) REPORT.—Not later than 18 months after
21 the date of enactment of this Act, the Comptroller
22 General of the United States shall submit to the
23 Committee on Health, Education, Labor, and Pen-
24 sions of the Senate and the Committee on Energy

1 and Commerce of the House of Representatives a re-
2 port containing—

3 (A) the results of the study conducted
4 under paragraph (1); and

5 (B) any relevant recommendations of the
6 Comptroller General for preparedness and re-
7 sponse efforts with respect to Zika virus and
8 other mosquito-borne diseases.

9 **SEC. 407. ADDITIONAL STRATEGIES FOR COMBATING ANTI-**
10 **BIOTIC RESISTANCE.**

11 Part B of title III of the Public Health Service Act
12 (42 U.S.C. 243 et seq.) is amended by inserting after sec-
13 tion 319E the following:

14 **“SEC. 319E-1. ADVISORY COUNCIL ON COMBATING ANTI-**
15 **BIOTIC-RESISTANT BACTERIA.**

16 “(a) DEFINITIONS.—In this section:

17 “(1) ACTION PLAN.—The term ‘Action Plan’
18 means the Action Plan described in section
19 319E(a)(1).

20 “(2) ADVISORY COUNCIL.—The term ‘Advisory
21 Council’ means the Presidential Advisory Council on
22 Combating Antibiotic-Resistant Bacteria established
23 by Executive Order 13676 of September 18, 2014
24 (79 Fed. Reg. 56931; relating to combating anti-
25 biotic-resistant bacteria).

1 “(3) NATIONAL STRATEGY.—The term ‘Na-
2 tional Strategy’ means the National Strategy for
3 Combating Antibiotic-Resistant Bacteria issued by
4 the White House in September 2014, and any subse-
5 quent update to such strategy or a successor strat-
6 egy.

7 “(b) ADVISORY COUNCIL.—The Advisory Council
8 shall provide advice, information, and recommendations to
9 the Secretary regarding programs and policies intended to
10 support and evaluate the implementation of Executive
11 Order 13676 of September 18, 2014 (79 Fed. Reg. 56931;
12 relating to combating antibiotic-resistant bacteria), includ-
13 ing the National Strategy, and the Action Plan.

14 “(c) MEETINGS AND DUTIES.—

15 “(1) MEETINGS.—The Advisory Council shall
16 meet as the Chair determines appropriate but not
17 less than twice per year, and, to the extent prac-
18 ticable, in conjunction with meetings of the task
19 force described in section 319E.

20 “(2) RECOMMENDATIONS.—The Advisory Coun-
21 cil shall make recommendations to the Secretary, in
22 consultation with the Secretary of Agriculture and
23 the Secretary of Defense, regarding programs and
24 policies intended to—

1 “(A) preserve the effectiveness of anti-
2 biotics by optimizing their use;

3 “(B) advance research to develop improved
4 methods for combating antibiotic resistance and
5 conducting antimicrobial stewardship, as de-
6 fined in section 319E(h)(3);

7 “(C) strengthen surveillance of antibiotic-
8 resistant bacterial infections;

9 “(D) prevent the transmission of anti-
10 biotic-resistant bacterial infections;

11 “(E) advance the development of rapid
12 point-of-care and agricultural diagnostics;

13 “(F) further research on new treatments
14 for bacterial infections;

15 “(G) develop alternatives to antibiotics for
16 animal health purposes;

17 “(H) maximize the dissemination of up-to-
18 date information on the appropriate and proper
19 use of antibiotics to the general public and
20 human and animal health care providers; and

21 “(I) improve international coordination of
22 efforts to combat antibiotic resistance.

23 “(3) COORDINATION.—The Advisory Council
24 shall, to the greatest extent practicable, coordinate
25 activities carried out by the Council with the Anti-

1 microbial Resistance Task Force established under
2 section 319E(a) (commonly referred to as the ‘Com-
3 battling Antibiotic-Resistant Bacteria Task Force’).”.

4 **SEC. 408. ADDITIONAL PURPOSES FOR GRANTS FOR CER-**
5 **TAIN TRAUMA CENTERS.**

6 Section 1241(a)(2) of the Public Health Service Act
7 (42 U.S.C. 300d–41(a)(2)) is amended to read as follows:

8 “(2) to further the core missions of such trau-
9 ma centers, including by addressing costs associated
10 with patient stabilization and transfer, trauma edu-
11 cation and outreach, coordination with local and re-
12 gional trauma systems, essential personnel and other
13 fixed costs, expenses associated with employee and
14 nonemployee physician services, trauma staff recruit-
15 ment and retention, ensuring surge capacity, trau-
16 ma-related emotional and mental health services,
17 and other investments needed to implement and
18 maintain Regional Health Care Emergency Pre-
19 paredness and Response Systems.”.

20 **SEC. 409. REVIEW OF THE BENEFITS OF GENOMIC ENGI-**
21 **NEERING TECHNOLOGIES AND THEIR POTEN-**
22 **TIAL ROLE IN NATIONAL SECURITY.**

23 (a) MEETING.—

24 (1) IN GENERAL.—Not later than 1 year after
25 the date of enactment of this Act, the Secretary of

1 Health and Human Services (referred to in this sec-
2 tion as the “Secretary”) shall convene a meeting to
3 discuss the potential role advancements in genomic
4 engineering technologies (including genome editing
5 technologies) may have in advancing national health
6 security. Such meeting shall be held in a manner
7 that does not compromise national security.

8 (2) ATTENDEES.—The attendees of the meeting
9 under paragraph (1)—

10 (A) shall include—

11 (i) representatives from the Office of
12 the Assistant Secretary for Preparedness
13 and Response, the National Institutes of
14 Health, the Centers for Disease Control
15 and Prevention, and the Food and Drug
16 Administration; and

17 (ii) representatives from academic,
18 private, and non-profit entities with exper-
19 tise in genome engineering technologies,
20 biopharmaceuticals, medicine, or bio-
21 defense, and other relevant stakeholders;
22 and

23 (B) may include—

24 (i) other representatives from the De-
25 partment of Health and Human Services,

1 as the Secretary determines appropriate;
2 and

3 (ii) representatives from the Depart-
4 ment of Homeland Security, the Depart-
5 ment of Defense, the Department of Agri-
6 culture, and other departments, as the Sec-
7 retary may request for the meeting.

8 (3) TOPICS.—The meeting under paragraph (1)
9 shall include a discussion of—

10 (A) the current state of the science of
11 genomic engineering technologies related to na-
12 tional health security, including—

13 (i) medical countermeasure develop-
14 ment, including potential efficiencies in the
15 development pathway and detection tech-
16 nologies; and

17 (ii) the international and domestic
18 regulation of products utilizing genome ed-
19 iting technologies; and

20 (B) national security implications, includ-
21 ing—

22 (i) capabilities of the United States to
23 leverage genomic engineering technologies
24 as a part of the medical countermeasure
25 enterprise, including current applicable re-

1 search, development, and application ef-
2 forts underway within the Department of
3 Defense;

4 (ii) the potential for state and non-
5 state actors to utilize genomic engineering
6 technologies as a national health security
7 threat; and
8 (iii) security measures to monitor and
9 assess the potential threat of genomic engi-
10 neering technologies and related tech-
11 nologies.

12 (b) REPORT.—Not later than 270 days after the
13 meeting described in subsection (a) is held, the Assistant
14 Secretary for Preparedness and Response shall issue a re-
15 port to the congressional committees of jurisdiction on the
16 topics discussed at such meeting, and provide rec-
17 ommendations, as applicable, to utilize innovations in
18 genomic engineering (including genome editing) and re-
19 lated technologies as a part of preparedness and response
20 activities to advance national health security. Such report
21 shall be issued in a manner that does not compromise na-
22 tional security.

23 **SEC. 410. CUT-GO OFFSET.**

24 The total amount authorized to be appropriated to
25 the Office of the Secretary of Health and Human Services

- 1 for each of fiscal years 2019 through 2023 is the amount
- 2 that is \$21,000,000 below the total amount appropriated
- 3 to such Office for fiscal year 2018.